

EPA Interim Guidance
for Implementing the
Small Business Regulatory Enforcement Fairness Act
and Related Provisions of the
Regulatory Flexibility Act

February 5, 1997

Prepared by the EPA SBREFA Task Force

NOTICE

The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on its analysis of the specific facts presented. This guidance may be revised without public notice to reflect changes in EPA's approach to implementing Small Business Regulatory Enforcement Fairness Act or the Regulatory Flexibility Act, or to clarify and update text.

Interim Guidelines for Implementing SBREFA

Table of Contents

Introduction: Overview of Agency Compliance Procedures

Flowchart: SBREFA Action Development Process Overview

Chapter 1: Analytical Requirements of the Regulatory Flexibility Act

Chapter 2: Identifying Small Entity Representatives

Chapter 3: Small Business Advocacy Review Panels

Chapter 4: Compliance Guides

Chapter 5: Congressional Review

Chapter 6: [Ed. Note: Reserved for Informal Small Entity Guidance (SBREFA §213)]

Chapter 7: [Ed. Note: Reserved for Periodic Review of Rules (RFA §610)]

Introduction

Overview of Agency Compliance Procedures

I. BACKGROUND and AGENCY POLICY

EPA has long been concerned with the effect of environmental regulations on small entities and has a strong record of reaching out to small entities and addressing their concerns in the Agency's rulemaking process. Under Administrator Carol Browner, the Agency has redoubled its efforts to enhance the involvement of stakeholders in the rule development process; emphasizing outreach to the regulated community, environmental groups, the general public and in particular, to the many small entities within these broader categories.

The President signed the Small Business Regulatory Enforcement Fairness Act (SBREFA) into law on March 29, 1996. SBREFA amended the Regulatory Flexibility Act (RFA) to strengthen the RFA's analytical and procedural requirements. SBREFA also made other changes to agency regulatory practice as it affects small entities. Finally, SBREFA established a new mechanism for expedited congressional review of virtually all agency rules.

Since SBREFA became law, EPA has worked diligently to develop and implement procedures necessary for full implementation and compliance with SBREFA's multiple and various provisions. To insure the Agency gave top priority to this effort, the Deputy Administrator and the Regulatory Policy Council established a cross-Agency Task Force consisting of five primary subgroups to develop comprehensive procedures for EPA's implementation of SBREFA. The subgroups covered each major SBREFA component immediately applicable to our day-to-day administration: 1) Regulatory Flexibility, 2) Small Entity Outreach, 3) Small Business Advocacy Review Panels, 4) Compliance Guides, and 5) Congressional Review. Each subgroup carefully reviewed the relevant statutory requirements and prepared recommendations and options for Agency review. The efforts of the Task Force subgroups are reflected in the chapters of this document.

Since its enactment in 1980, the RFA has required every federal agency to prepare regulatory flexibility analyses for any notice-and-comment rule it issues, unless the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities." One important function of this guidance is to establish workable criteria for determining whether a particular rule will not have a "significant impact" on a "substantial number" of small entities. Prior to the enactment of SBREFA, EPA exceeded the requirements of the RFA by instructing regulatory managers to prepare regulatory flexibility analyses for every rule that would have any impact, no matter how minor, on any number, no matter how small, of small entities. It remains our policy that program offices should assess the impact of every rule on small entities and minimize any impact to the extent feasible, regardless of the size of the impact or number of small entities affected. In view of the changes made by

SBREFA, however, the Agency has decided to implement the RFA as written; that is, regulatory flexibility analyses as specified by the RFA will **not** be required if the Agency certifies that the rule will not have significant economic impact on a substantial number of small entities. This approach will allow EPA to manage its scarce resources such that the Agency can continue considering the potential small entity impacts of all its rules while preparing full regulatory flexibility analyses for those rules warranting such analyses under the RFA.

II. OVERVIEW

When you initiate a regulatory development project, SBREFA and RFA compliance should be near the top of the list of issues you address in your project plan or Analytic Blueprint¹. To help you understand how the requirements of SBREFA and RFA fit into the Agency's Action Development Process², we prepared an overview flowchart and it appears below. Keep in mind that although the chapters are organized sequentially, some SBREFA compliance activities must be performed concurrently and the flowchart illustrates this.

A. Analyzing a Rule's Impact on Small Entities

As you start the rule development process, the first thing you need to do for SBREFA and RFA compliance is determine what, if any, impact your rule will have on small entities. In order to do this, you need to screen your proposed **and** final rules by answering a series of questions posed and discussed in detail in *Chapter 1* of this guidance:

- Q1. Is the rule subject to notice-and-comment rulemaking requirements?
- Q2. What types of entities will be subject to the rule?
- Q3. What types of small entities will be subject to the rule, if any?
- Q4. Will any small entities potentially be subject to the rule?
- Q5. Will small entities be adversely affected by the rule?
- Q6. Will the rule have a significant economic impact on a substantial number of small entities?

B. Implementing Small Entity Outreach

If the screening analysis of your rule indicates that the rule will have some impact on some small entities, *Chapter 2* will provide you with information and guidance for identifying possible representatives of potentially affected small entities.

¹ See "Guidance for Analytic Blueprints", 06/15/94, or contact OPPE's Regulatory Management Division (RMD) on 202-260-5480

² See "EPA's Action Development Process: Regulatory and Policy Development; Guidelines for Implementation", July 1994, also available from RMD.

C. Small Business Advocacy Review Panels

If your **proposed** rule will **not** be certified as having no significant economic impact on a substantial number of small entities, SBREFA imposes some additional requirements for working with the potentially affected community, as well as the Small Business Administration and the Office of Management and Budget. In **Chapter 3** you will find detailed information about how you should go about complying with the requirement to convene a Small Business Advocacy Review Panel.

D. Small Entity Compliance Guides

If your **final** rule is **not** certified as having no significant economic impact on a substantial number of small entities, SBREFA also requires you to prepare a small entity compliance guide. **Chapter 4** answers questions regarding what constitutes such a guide and provides a template to use in designing a compliance guide for your rule.

E. Congressional Review

Aside from the foregoing requirements which relate to the impact your rule will have on small entities, SBREFA also requires that the Agency submit virtually **all** of its final actions to both houses of Congress and GAO for review. **Chapter 5** explains how congressional review works and what you must include in your rulemaking package for purposes of congressional review.

F. Ongoing Informal Small Entity Guidance

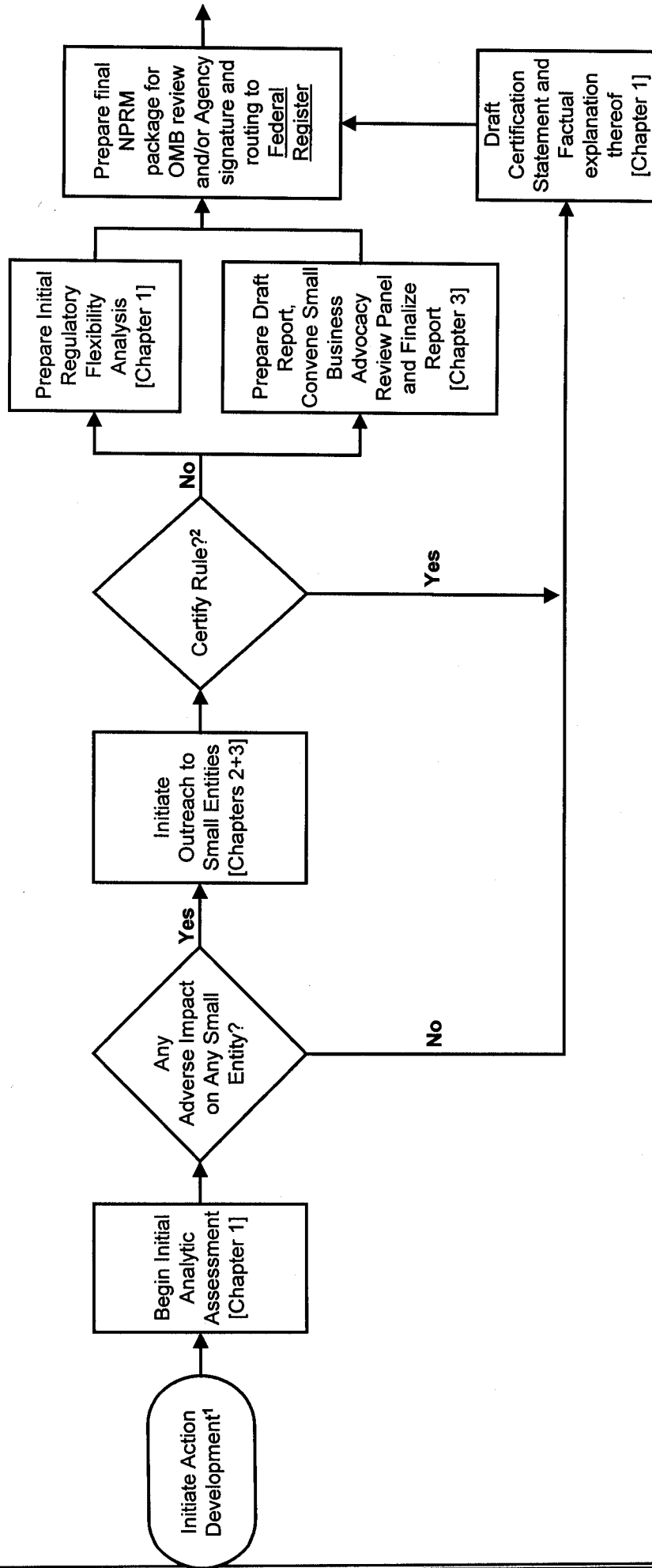
When planning for the post-promulgation stage of your rule, refer to the discussion in **Chapter 6** regarding the SBREFA provision on giving informal advice to small entities in response to inquiries. You should keep in mind that information and advice you provide to small entities can later be used in any civil or administrative action against a small entity as evidence of the reasonableness and appropriateness of any proposed fines, penalties, or damages.

G. Periodic Review of Rules

The SBREFA amendments to RFA made judicially reviewable the provisions found in §610 requiring the Agency to review rules which have or will have a significant economic impact upon a substantial number of small entities. **Chapter 7** explains the Agency's plans for continued and re-invigorated compliance with this requirement.

We hope you find the guidance in this document helpful and easy to use. We plan to update it as needed, so if you have comments or suggestions for improvements, please send them to Stuart Miles-McLean in the Regulatory Management Division of OPPE.

SBREFA Action Development Process Overview



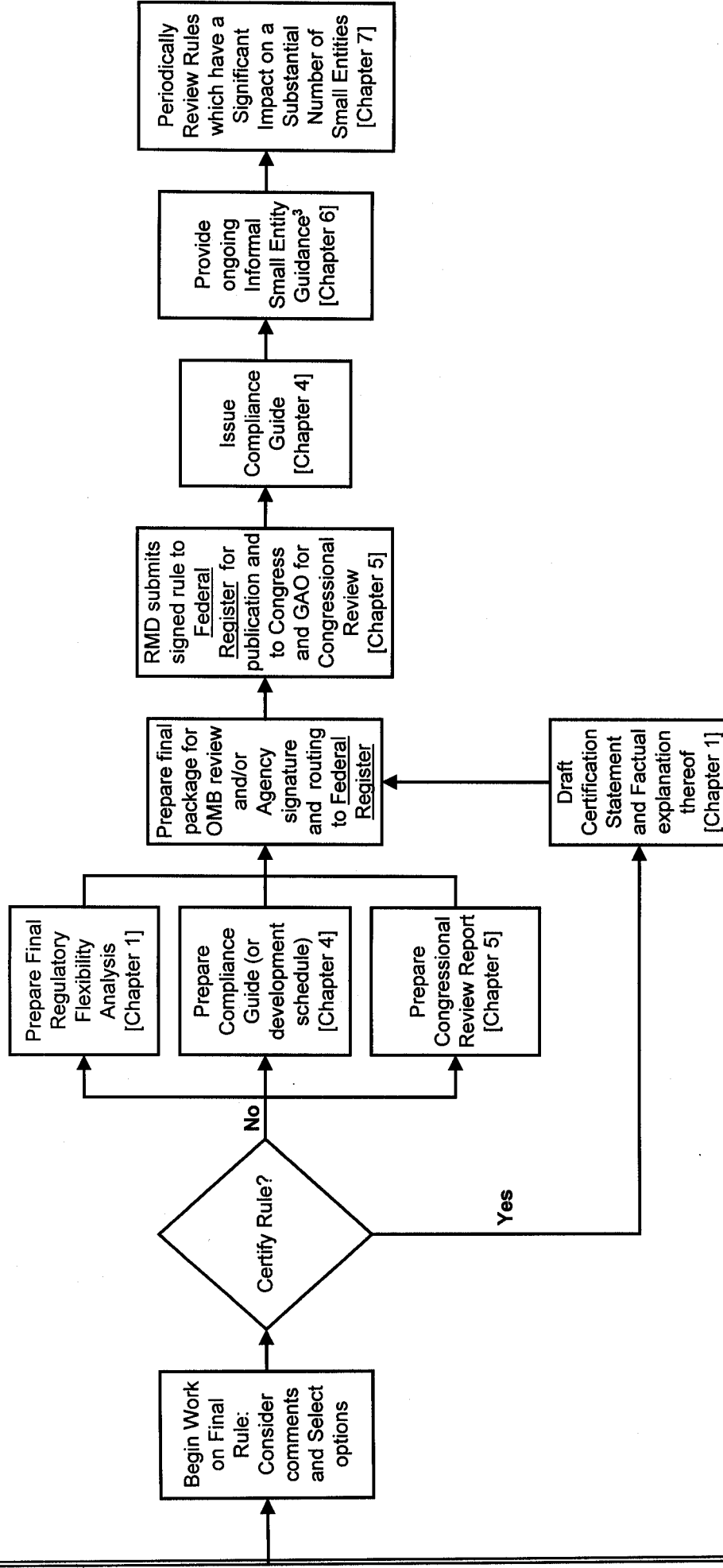
Notes:

General: References to "Chapters" in the flowchart refer to the chapters in the attached guidance document (see Table of Contents).

¹ In keeping with the scope of SBREFA, the only actions to which this flowchart applies are rules (as opposed to adjudications) that apply to unnamed entities and/or are required to undergo notice-and-comment rulemaking procedures. As explained more fully in Chapter 1, only rules of general applicability are subject to the congressional review provisions of SBREFA, and only rules subject to notice-and-comment requirements are subject to the regulatory flexibility analysis requirements of the Regulatory Flexibility Act as amended by SBREFA. Consult with OGC regarding applicability for each action.

² Under the Regulatory Flexibility Act, the Agency must prepare an Initial Regulatory Flexibility Analysis (IRFA) and meet other requirements, unless it certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities"

SBREFA Action Development Process Overview



Notes:

³ SBREFA Section 213: Informal Small Entity Guidance (a) it shall be the practice of the agency to answer inquiries by small entities concerning information on, and advice about, compliance with such statutes and regulations, interpreting and applying the law to specific sets of facts supplied by the small entity. In any civil or administrative action against a small entity, guidance given by an agency applying the law to facts provided by the small entity may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages sought against such small entity.

Chapter 1

Analytical Requirements of the Regulatory Flexibility Act

Section	Subject	Page
I.	Introduction	1
II.	Statutory Background	2
III.	Analyzing a Rule's Impact on Small Entities	8
IV.	Fulfilling the RFA's Analytical Requirements	20

I. INTRODUCTION

Since its passage in 1980, the Regulatory Flexibility Act (RFA) has generally required every federal agency to prepare regulatory flexibility analyses for any notice-and-comment rule it issues, **unless** the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities," which include small businesses, small governments and small nonprofit organizations. The RFA was amended in 1996 by the Small Business Regulatory Enforcement Fairness Act (SBREFA) in ways that strengthened the RFA's analytical and procedural requirements. This chapter of the guidance provides EPA program offices with advice and direction on how to comply with the analytical requirements of the RFA as amended by SBREFA and the Agency's policy for implementing those requirements. In many respects, the advice and direction provided here go beyond what the law requires, and instead reflect Agency policy about how best to ensure that small entity concerns are considered in the rulemaking process. As the Agency gains additional experience implementing the RFA as amended by SBREFA, it will review this guidance and revise it as appropriate.

Prior to SBREFA's enactment, the Agency issued guidance regarding implementation of the RFA. The most recent guidance (dated April 1992) advised EPA program offices to prepare regulatory flexibility analyses for any rule that would have "any impact" on "any number" of small entities, which is more than the RFA requires. It remains the Agency's policy that program offices should assess the impact of every rule on small entities and minimize any impact to the extent feasible, regardless of the size of the impact or number of small entities affected. Further, the outcome of that assessment and the steps taken to minimize any impact should be discussed or summarized in the preamble to the rule. In view of the changes made by SBREFA, however, the Agency has decided to implement the RFA as written; that is, regulatory flexibility analyses

as specified by the RFA will not be required if the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

This chapter of the guidance suggests criteria and thresholds for determining whether a particular rule will not have a significant economic impact on a substantial number of small entities. The guidance recognizes that there can be no one-size-fits-all methodology for making this determination. It therefore recommends specific approaches but leaves Agency program offices and senior managers flexibility to use alternative methods or reach different conclusions where appropriate in the context of a particular rule for reasons stated in the rulemaking record.

Where the Agency does **not** certify that a rule will have no significant economic impact on a substantial number of small entities, regulatory flexibility analyses meeting the applicable statutory requirements must generally be prepared for the rule. This guidance also provides advice and direction on how to prepare such analyses. It bears repeating, however, that even where the Agency certifies that a rule will **not** have significant economic impact on a substantial number of small entities, the Agency's policy is that an assessment of the rule's impact on any small entities must still be made and efforts to minimize that impact undertaken. The Agency is committed to maintaining a rulemaking process that avoids placing any undue regulatory burden on any small entities.

II. STATUTORY BACKGROUND

A. What is the purpose of the RFA?

The purpose of the RFA is to ensure that in developing rules, agencies identify and consider ways of tailoring regulations to the size of the regulated entities to minimize any significant economic impact a rule may impose on a substantial number of small entities. The RFA does not require that an agency necessarily minimize a rule's impact on small entities if there are legal, policy, factual or other reasons for not doing so. The RFA requires only that agencies determine, to the extent feasible, the rule's economic impact on small entities, explore regulatory options for reducing any significant economic impact on a substantial number of such entities, and explain its ultimate choice of regulatory approach.

B. What are "small entities"?

The RFA defines small entities as including "small businesses," "small governments" and "small organizations." The RFA further defines each type of small entity, and authorizes agencies to adopt alternative definitions where appropriate in accordance with specified procedures.

1. What is a "small business"?

The RFA references the definition of "small business" found in the Small Business Act,

which itself authorizes the Small Business Administration (SBA) to further define "small business" by regulation. The SBA's small business definitions are codified at 13 CFR 121.201, and the SBA reviews and reissues those definitions every year.³ The SBA defines small business by category of business using Standard Industrial Classification (SIC) codes, and in the case of manufacturing, generally defines small business as a business having 500 employees or less. For many types of manufacturing, however, the SBA's size standards define small business as a business having up to 750, 1000 or 1500 employees, depending on the particular type of business. In the case of agriculture, mining, and electric, gas and sanitary services, the SBA size standards generally define small business with respect to annual receipts (from \$0.5 million for crops to \$25 million for certain types of pipelines).

The RFA also authorizes any agency to adopt and apply an alternative definition of small business "where appropriate to the activities of the agency" after consulting with the Chief Counsel for Advocacy of the SBA and after opportunity for public comment. The agency must publish any alternative definition in the Federal Register.

2. What is a "small government"?

The RFA defines "small governmental jurisdiction" as the government of a city, county, town, school district or special district with a population of less than 50,000. Similar to the definition of small business, the RFA authorizes agencies to establish alternative definitions of small government after opportunity for public comment (consultation with the SBA is **not** required). Any alternative definition must be "appropriate to the activity of the agency" and "based on such factors as location in rural or sparsely populated areas or limited revenues due to the population of such jurisdiction." Any alternative definition must be published in the Federal Register.

3. What is a "small organization"?

The RFA defines "small organization" as any "not-for-profit enterprise which is independently owned and operated and is not dominant in its field." Here again, agencies are authorized to establish alternative definitions "appropriate to the activities of the agency" after providing an opportunity for public comment (consultation with the SBA is **not** required). Any alternative definition must be published in the Federal Register.

C. What types of regulatory actions are subject to the RFA's analytical requirements?

As a threshold matter, the RFA requirement to prepare a regulatory flexibility analysis (or a certification of no significant economic impact on a substantial number of small entities)

³SBA's most recent revisions to its "size standards" can be found in the January 31, 1996 Federal Register (61 FR 3175). Several minor corrections were published on February 20, 1996 (61 FR 6421). The SBA has an Internet site with the current version of its size standards at "http://www.sbaonline.sba.gov/gopher/Financial-Assistance/Size-Standards."

applies only to **proposed rules subject to notice-and-comment rulemaking requirements** under the Administrative Procedure Act (APA) or any other statute and to **final rules subject to notice-and-comment rulemaking requirements** under the APA or any other statute and issued under the APA. Agency actions that are **not** rules (e.g., orders or adjudication) and rules that the Agency is **not required** to propose before promulgating are **not** subject to the RFA requirement to prepare either a regulatory flexibility analysis or a certification.

Most EPA rulemakings are subject to the APA, which generally requires that an agency propose and take comment on a rule before issuing it. The APA, however, exempts from notice-and-comment requirements any rule of agency organization, procedure or practice and any rule for which the agency finds "for good cause" that notice and an opportunity to comment are "impracticable, unnecessary, or contrary to the public interest."

The procedures for some EPA rulemakings are governed by other statutes. For example, many Clean Air Act (CAA) rulemakings are subject to the procedural requirements of section 307(d) of the CAA instead of the APA. In such cases, those statutes should be consulted to determine if the rule is subject to the RFA analytical requirements.

It should be noted that "direct final rules" -- rules that the Agency issues as final rules without first proposing them, but that are converted to proposed rules if anyone files an adverse comment -- are generally subject to notice-and-comment requirements.

D. What are the RFA's analytical requirements?

The RFA requires that an agency prepare an **initial regulatory flexibility analysis (IRFA)** for a **proposed rule**, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Similarly, the RFA requires that an agency prepare a **final regulatory flexibility analysis (FRFA)** for a **final rule**, unless the agency head certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA further requires that an agency provide factual support for any certification it makes. In short, an agency must prepare for every proposed **and** final rule subject to the RFA's analytical requirements a regulatory flexibility analysis except to the extent the agency prepares and supports a certification that the rule will not have a significant economic impact on a substantial number of small entities.⁴

⁴Preparing an IRFA for a proposed rule does not legally foreclose certifying that the final rule will have no significant economic impact on a substantial number of small entities. Similarly, certifying that the proposed rule will have no significant economic impact on a substantial number of small entities does not legally foreclose preparing a FRFA for the final rule. In applying the analysis-or-certification requirement separately to proposed and final rules, the RFA implicitly recognizes that an agency's findings about small entity impacts may change from the proposed to final rulemaking stage, as the agency learns more about potential impacts from public comments on the proposed rule and makes changes to the final rule.

1. How does the RFA define "significant economic impact on a substantial number of small entities"? What are the legal requirements for certifying a rule?

The RFA does not define "significant economic impact on a substantial number" of small entities. Agencies therefore have substantial discretion in determining what is not a significant economic impact on, and a substantial number of, small entities. This interim guidance suggests analytical methods, criteria and thresholds for making that determination. As noted above, if an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, it must support that certification with a factual explanation. Implementation of this guidance will provide the factual predicate for certifying a rule.

The RFA authorizes the head of an agency to certify a rule. EPA's Administrator has delegated that authority to the Agency official who has been delegated the authority to sign the rule for which a certification has been prepared, except that the authority to certify under the RFA cannot be redelegated below the Office Director level.

When an agency certifies a rule, it must publish that certification in the Federal Register at the same time it publishes the proposed or final rule to which the certification applies.

2. What are the legal requirements for Initial Regulatory Flexibility Analyses (IRFAs)?

When an agency cannot or does not certify that a proposed rule will not have a significant economic impact on a substantial number of small entities, it must prepare an IRFA for the proposed rule.⁵ While an agency may delay or even waive preparation of an IRFA under emergency circumstances, it generally must complete the IRFA in time for the IRFA or a summary of it to be published along with the proposed rule.⁶ An IRFA must contain the following:

- an explanation of why the rule may be needed;
- a short statement of the objectives of and legal basis for the proposed rule;

[NOTE that these first two items are virtually always addressed by the NPRM preamble or other rulemaking documents, so the IRFA need not repeat this information but may simply cross-reference the preamble or other documents]

⁵When EPA does **not** certify a proposed rule, it must also convene a Small Business Advocacy Review Panel. A suggested approach for implementing the review panel requirement is contained in Chapter 3 of this guidance.

⁶The RFA authorizes an agency head to waive or delay the completion of an IRFA if the agency publishes in the Federal Register, by the time the final rule is published, a finding supported by reasons that the final rule is being promulgated in response to an emergency that makes compliance or timely compliance with the IRFA requirement impracticable.

- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the proposed reporting, record keeping and other compliance requirements, including an estimate of the types of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- an identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap or conflict with the proposed rule; and
- a description of "any significant regulatory alternatives" to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant economic impact of the proposed rule on small entities; the analysis is to discuss significant regulatory alternatives such as:
 - ▶ establishing different compliance or reporting requirements or timetables that take into account the resources of small entities;
 - ▶ clarifying, consolidating or simplifying compliance and reporting requirements under the rule for small entities;
 - ▶ using performance rather than design standards; and
 - ▶ exempting small entities from coverage of the rule or any part of the rule.

As indicated above, an IRFA or a summary of the IRFA must be published in the Federal Register along with the proposed rule for which it was prepared. IRFAs are subject to public comment.

3. What are the legal requirements for Final Regulatory Flexibility Analyses (FRFAs)?

When an agency cannot or does not certify that a final rule will not have a significant economic impact on a substantial number of small entities, it must prepare a FRFA for the final rule. While the agency may delay the preparation of a FRFA under emergency circumstances, it generally must finish the FRFA in time to publish it or a summary of it along with the final rule.⁷ A FRFA must contain the following:

⁷The RFA authorizes an agency head to delay the completion of a FRFA for up to 180 days after the final rule is published in the Federal Register, if the agency head publishes in the Federal Register along with the final rule a finding supported by reasons that the final rule is being promulgated in response to an emergency that makes timely compliance with the FRFA requirement impracticable.

- a short statement of the need for, and objectives of the rule;
- a summary of the significant issues raised by the public commenters in response to the IRFA, a summary of agency's response to those issues and a statement of any changes to the rule made as a result of those comments;

[NOTE that the first item is virtually always addressed by the final rule's preamble, so the FRFA may simply cross-reference the preamble; to the extent the summary and response to comments document prepared for the rule fulfills the requirements of the second item, the FRFA may also cross-reference that document]

- a description of and an estimate of the number of small entities to which the rule will apply, or an explanation of why an estimate is unavailable;
- a description of the projected reporting, record keeping and other compliance requirements of the rule, including an estimate of the types of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

[NOTE that the foregoing item has a counterpart in the IRFA. To the extent the final rule adopts the proposed rule unchanged, the FRFA may cross-reference the IRFA for purposes of complying with this requirement, except as public comments indicate that the IRFA's analysis must be changed]

- a description of "the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant regulatory alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

As indicated above, a FRFA or a summary of the FRFA must be published in the Federal Register along with the final rule for which it was prepared. A copy of the FRFA must also be made available to the public.

E. May courts review agency compliance with the RFA?

SBREFA made agency compliance with many of the RFA's requirements judicially reviewable. With respect to the RFA's analytical requirements, small entities adversely affected by a final rule may now obtain judicial review of any certification of no significant impact the agency made or any FRFA the agency prepared. While compliance with the IRFA requirement is not judicially reviewable, preparation of a solid IRFA will be important to preparing a legally defensible FRFA.

III. ANALYZING A RULE'S IMPACT ON SMALL ENTITIES

This section describes a screening process for determining whether a regulatory flexibility analysis or a certification of no significant impact should be prepared for a proposed or final rule.⁸ The screening process is laid out step-by-step so that the relevant issues are addressed in an order that will ensure that appropriate determinations are made. The process should be followed for both the proposed and final version of a rule, since the RFA generally requires that a regulatory flexibility analysis or certification be prepared for each version. The last section describes how to fulfill the RFA's analytical requirements depending on whether the screening analysis indicates that a regulatory flexibility analysis or a certification should be prepared.

Phrased as questions, the steps of the screening process are as follows:

Q 1. Is the rule subject to notice-and-comment rulemaking requirements?

As noted above, if a rule is **not** required to undergo notice-and-comment rulemaking procedures, it is **not** subject to the RFA's analytical requirements and the Agency need not prepare an IRFA **or** a certification of no significant economic impact on a substantial number of small entities. However, as a matter of Agency policy, even if a rule is **not** subject to the RFA, where the program office foresees that the rule will have an adverse economic impact on small entities, it should assess and make efforts to minimize that impact.

Even when a rule is **not** subject to the RFA, the preamble to the proposed rule, if any, and the preamble of the final rule should include a "Regulatory Flexibility" section that explains 1) that the rule is not subject to the RFA, and 2) what adverse impact, if any, the rule will have on small entities and what the Agency has done to minimize those impacts. For rules not subject to the RFA, suggested language for the rule's preamble is as follows:

The Agency has determined that the rule being [proposed OR issued] today is not subject to the Regulatory Flexibility Act (RFA), which generally requires an agency to conduct a regulatory flexibility analysis of any significant impact the rule will have on a substantial number of small entities. By its terms, the RFA applies only to rules subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute. Today's rule is not subject to notice and comment requirements under the APA or any other statute. [Insert at this point one or two sentences explaining why the rule isn't subject to notice-and-comment requirements -- e.g., the rule is subject to the APA, but the Agency has invoked the "good cause" exemption under APA §553(b), or the rule is

⁸As noted earlier, the RFA requirement for a regulatory flexibility analysis or a certification applies only to legally enforceable rules. If the action the Agency is taking is other than a rule, the RFA does not apply and the screening analysis described in this section of the guidance need not be conducted.

subject not to the APA but to [name the statute that applies], which does not require that the Agency provide notice and comment before issuing this rule.]

The Agency nonetheless has assessed the potential of this rule to adversely impact small entities. [Insert at this point one or two sentences either describing what we think those impact will be and what the Agency has done to address them, or explaining why the rule will not adversely impact any small entities.]

Q 2. What types of entities will be subject to the rule's requirements?⁹

If the rule is subject to notice-and-comment rulemaking requirements, the program office should next identify what types of entities (regardless of size) would be subject to the rule's requirements, as follows:

- a. **Businesses:** Identify the types of businesses potentially subject to the rule's requirements and determine the SIC code for those types of businesses, since the SBA's size standards apply to specified SIC codes.
- b. **Governments:** Identify all forms of small governments potentially subject to the rule, including cities, counties, towns, townships, villages, tribes and special districts.

⁹The RFA requires analysis of a rule's economic impact on the small entities that **will be subject to the rule's requirements**. Indeed, an IRFA or FRFA cannot be prepared for a rule that does not establish requirements applicable to small entities. As noted in the "Statutory Background" section of this chapter, the RFA requires that an IRFA or FRFA identify the types, and estimate the numbers, of small entities "to which the proposed [or final] rule will apply," and describe the rule "requirements" to which small entities "will be subject" and any regulatory alternatives, including exemptions and deferrals, which would lessen the rule's burden on small entities.. See sections 603 and 604 of the RFA. Rules that do not establish requirements applicable to small entities (e.g., rules establishing or revising national ambient air quality standards under the CAA or water quality standards under the Clean Water Act) are thus not susceptible to RFA analysis and may be certified as not having a significant economic impact on a substantial number of small entities, within the meaning of the RFA.

For a rule that will establish requirements applicable to small entities, only the impacts of the rule on the small entities subject to the rule's requirements need to be analyzed for RFA purposes. In the case of a rule applying to auto service stations, for example, it is not necessary to analyze the potential impact of the rule on suppliers of service stations, except to the extent that the rule may result in higher costs to suppliers that will be passed along to service stations.

- c. **Nonprofit Organizations:** Identify what entities such as nonprofit hospitals, colleges, universities and research institutions are potentially subject to the rule.

Q 3. What types of *small* entities, if any, will be subject to the rule's requirements?

Of the types of entities potentially subject to any of the rule's requirements, the program office should next determine the extent to which those types of entities include **small** entities. In identifying small entities, the program office should apply the RFA definitions of small entities or, where appropriate, any appropriate alternative definitions¹⁰ that the Agency has adopted or intends to adopt in accordance with the RFA, as follows:

- a. **Small businesses:** Determine whether the Agency properly adopted (i.e., after consulting with SBA and an opportunity for public comment) any alternative definition for any of the types of small businesses potentially subject to the rule, in the context of the regulatory program to which the rule relates or any other EPA regulatory program.
- If the Agency has properly adopted an alternative definition, the program office may use that alternative definition to the extent it (continues to) make sense in the context of the relevant regulatory program. If using the existing definition does not make sense, the program office may develop a different alternative definition in accordance with the RFA or use the SBA definition instead.
 - If the Agency has not adopted any alternative definition, the program office may develop an alternative definition in accordance with the RFA or use the SBA definition instead.
- b. **Small governments:** Apply the statutory definition or any alternative definition the program office intends to establish (the Agency has not previously established any alternative definitions of small governments for RFA purposes).
- c. **Small organizations:** Apply the statutory definition or any alternative definition it intends to establish (the Agency has not previously established any alternative definitions of small organizations for RFA purposes).

¹⁰The RFA grants agencies broad discretion to develop and apply alternative definitions of small business, small governments and small nonprofit organizations. In exercising this discretion, however, care should be taken to develop alternative definitions that identify small entities as opposed to entities that emit a small volume of pollution. It may be appropriate for the Agency to provide regulatory flexibility or relief to small-volume polluters on general policy grounds, but the focus of the RFA is on entities whose size or resources are small in comparison to other entities of their type.

Q 4. Will *any* small entities potentially be subject to the rule's requirements?

If **no** small entities will be subject to any of the rule's requirements, the program office may certify that the proposed and final rules will **not** have a significant economic impact on a substantial number of small entities on that basis. The certifications should be published and explained in the preambles of the proposed and final rules and supported in the rulemaking record as appropriate. No further analysis is required to support the certifications, unless the Agency receives comments on the proposed rule's certification that indicate its basis is flawed. If one or more small entities will be subject to the rule's requirements, further analysis is required as outlined below.

Q 5. Will small entities be *adversely* affected by the rule's requirements?

EPA believes that only rules that will have a significant **adverse** economic impact on small entities require an IRFA and FRFA, since the primary purpose of both analyses is to identify and address regulatory alternatives "which **minimize** any significant economic impact of the proposed [or final] rule on small entities." (sections 603 and 604, emphasis added). Thus, rules that **relieve** regulatory burden, or otherwise have a positive economic effect on the small entities subject to the rule, do not require an IRFA or a FRFA.

If the rule will not have any adverse effect on any small entity subject to the rule's requirements, the program office may certify that the proposed and final rules will not have a significant economic impact on a substantial number of small entities on that basis. The certifications should be published and explained in the preambles of the proposed and final rules and supported in the rulemaking record as appropriate. No further analysis is required to support the certification, unless the Agency receives comments on the proposed rule's certification that indicate its basis is flawed. If one or more small entities subject to the rule will be adversely affected by the rule, further analysis is required as outlined below.

It should be noted that a particular rule may reduce some burdens on small entities and create or increase others. Where the rule reduces the burden on one type of small entity while increasing the burden on another type of small entity, the decrease and increase in burden generally may **not** be netted. Where the same types of small entities will experience both the decrease and increase in burden, netting may be appropriate.

Q 6. Will the rule have a *significant economic impact on a substantial number of small entities*?

For a proposed or final rule that will have an adverse effect on one or more small entities, the program office must next determine the extent of the impact and the number of small entities so impacted. Both qualitative information and quantitative analysis will be relevant in making this determination.

a. What is the role of qualitative information?

Before investing in detailed quantitative analysis, the program office should attempt to describe the steps a small entity will have to take to comply with the requirements of the rule. In so doing, the program office will better clarify the nature of the impacts (e.g., installation of new technological processes, institution of new maintenance practices). It may then be able to deduce whether the potential impacts are of sufficient magnitude and scope to warrant preparation of an IRFA or FRFA.

Where a qualitative assessment indicates that a rule is likely to have a significant economic impact on a substantial number of small entities, the program office may choose to prepare an IRFA and FRFA on that basis and so avoid the need for a full screening analysis. Where a qualitative assessment indicates that a rule will **not** have a significant economic impact on a substantial number of small entities, the program office may be able to certify the rule on that basis or may need to conduct a quantitative analysis to confirm the results of the qualitative assessment. For example, where the information necessary to conduct a quantitative analysis is not reasonably available, it may be appropriate to certify the rule based on the qualitative assessment alone. Since the decision to certify a rule is judicially reviewable, the program office should expect that certifying a rule will usually require quantitative analysis when quantitative analysis is feasible. The program office should consult with the Small Business Advocacy Chairperson when it anticipates relying on qualitative analysis to certify a rule.

b. How should a quantitative analysis be conducted?

I. *What measures of economic impact should be used?*

The table below (Table 1) lists suggested economic criteria for assessing the impact of a rule on small entities. The suggested criteria are drawn from standard economic analyses and vary by type of small entity in view of the different economic characteristics of small businesses, governments and nonprofit organizations. Further, for each type of small entity, several different criteria are listed. The criteria vary in terms of the type of data involved, and thus a program office may choose to apply one criterion over the others based on the type of information available. The table nevertheless indicates a preferred criterion for each type of small entity (i.e., B1, G1 and N1). Where the program office has the necessary information, it should generally use the preferred criterion. The program office may nonetheless use one of the other criteria, or even a criterion not included in the table, where it has sound reasons for doing so and it explains those reasons in the rulemaking record.

ii. *To what extent should the analysis differentiate between different kinds of small businesses, small governments or small nonprofits?*

A rule may apply to more than one kind of business, government or nonprofit organization. For example, a rule may apply the same requirements to printers, dry cleaners and auto-body shops. In assessing the impact of such a rule on "small business," it may be

appropriate to analyze the rule's impact on each kind of business separately, particularly where the rule may impose significantly higher costs on some kinds of businesses than on others.

TABLE 1: Recommended Quantitative Criteria for Evaluating the Economic Impact of a Rule on Small Entities	
Type of Entity and Criteria (preferred criteria in <i>bold italics</i>)	
SMALL BUSINESSES	
B.1	<i>Annualized compliance costs as a percentage of sales ("Sales Test")</i>
B.2	Debt-financed capital compliance costs relative to current cash flow ("Cash Flow Test")
B.3	Annualized compliance costs as a percentage of before-tax profits ("Profit Test")
SMALL GOVERNMENTS	
G.1	<i>Annualized compliance costs as a percentage of annual government revenues ("Revenue Test")</i>
G.2	Annualized compliance costs to household (per capita) as a percentage of median household (per capita) income ("Income Test")
SMALL NONPROFIT ORGANIZATIONS	
N.1	<i>Annualized compliance costs as a percentage of annual operating expenditures ("Expenditure Test")</i>
N.2	Annualized compliance costs as a percentage of total assets ("Asset Test")

- iii. *For proposed rules, what should be analyzed if more than one regulatory approach is being proposed or seriously considered?*

For proposed rules, one of the criteria listed, or any other economic criterion the program office decides to use, should be applied to the regulatory approach being proposed. Where the program office plans to propose in the alternative (i.e., propose two or more approaches from among which one will be selected for promulgation in the final rule), it should apply the criteria to each of the proposed alternatives or at least to the alternative that would likely have the greatest impact on small entities.

Similarly, where the program office plans to propose one regulatory approach but seek comment on variations of that approach or on different approaches altogether, it might be useful to analyze not only the proposed approach but also the most potentially burdensome variation or approach that has a significant chance of being promulgated. Doing so will avoid the situation where adoption of an alternative requires preparation of a FRFA without the benefit of an IRFA or public comment on an IRFA. While the RFA does not require that an agency re-propose a rule with an accompanying IRFA in such situations, EPA may decide in particular cases that for policy reasons the rule should be re-proposed with an accompanying IRFA. The workgroup

chair should contact the program office's steering committee representatives and OGC contact when uncertain about the appropriate scope of an IRFA for a proposed rule.

- iv. *In assessing costs, should compliance with existing legal requirements be assumed? Should incremental or cumulative costs be assessed?*

In calculating the costs the rule will impose on small entities, the program office should presume that small entities (like all potentially covered entities) are complying with all existing statutory or regulatory requirements that are applicable to them. In the case of a rule revising an existing rule, the program office should assess only the incremental cost of the rule revision. In general, the cost of the existing rule was assessed, and a regulatory flexibility analysis or certification prepared, when that rule was developed.

- c. As measured using the economic criteria suggested above, what degree and extent of impact constitute "a significant economic impact on a substantial number of small entities"?

Application of the criteria suggested above to a particular rule will yield quantitative estimates of the rule's impact on small entities. Table 2 presents a matrix that categorizes the rule based on the magnitude of its impact (as measured using the preferred criteria in Table 1¹¹) **and** the number of entities expected to experience an impact of a particular magnitude.¹² Each category establishes either a process for determining, or a presumption regarding, whether the rule can be certified as having no significant impact on a substantial number of small entities. The categories further specify the Agency official authorized to rebut any applicable presumption. The categories are as follows:

Category 1: The rule is presumed **not** to have a significant economic impact on a substantial number of small entities, but the Assistant Administrator of the

¹¹When applying one of the alternative quantitative criteria listed in Table 1, the program office must consult with the Small Business Advocacy Chairperson (SBAC) and other relevant Agency offices (including those identified by the SBAC) in determining the level at which the impact may warrant preparation of a regulatory flexibility analysis.

¹²As explained previously, the legal test for certifying a rule is whether the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities." The test thus has two steps -- first, will the impact on any small entities subject to the rule be significant, and second, will the number of small entities significantly impacted be substantial? The Agency may certify a rule if its impact is significant but only with respect to a small number or percentage (i.e., not a "substantial number") of the small entities subject to the rule's requirements. The Agency may also certify a rule if its impact falls on a substantial number of small entities, but its impact is not significant. The Agency may not certify a rule if a substantial number of the small entities subject to the rule's requirements will be significantly impacted by the rule.

program office developing the rule may, at his or her discretion, decide to prepare a regulatory flexibility analysis for the rule.

Category 2: No presumption applies. If the program office developing the rule believes the rule should be certified as **not** having a significant impact on a substantial number of small entities, it must so recommend through its steering committee representative to the Small Business Advocacy Chairperson (SBAC) and provide the SBAC with information and analysis supporting its recommendation. The SBAC will then determine whether he or she agrees with the program office's recommendation. Any disputes between the program office and the SBAC will be referred to the Deputy Administrator for resolution.

Category 3: The rule is presumed to be ineligible for certification, so an IRFA or FRFA should be prepared. However, the Assistant Administrator for the program office developing the rule may recommend to the Deputy Administrator (DA) that the rule nevertheless be certified as not having a significant impact based on information and analysis developed by the program office.¹³ The SBAC will inform the DA of his or her views.

The scope of each category is defined by various thresholds for three variables: the magnitude of the impact, the absolute number of small entities that will experience that impact, and the percentage of all the small entities subject to the rule that will experience that impact. It is important to keep in mind, however, that the thresholds are only guidelines for determining whether a rule will not have a significant impact on a substantial number of small entities. The RFA itself does not establish a formula for making this determination, and indeed, it would be impossible to develop a formula that would yield an appropriate answer in the context of every rule. For that reason, the thresholds are used to define categories that establish no more than a presumption; program offices and the Agency as a whole will have to exercise judgment in deciding whether to prepare an IRFA or FRFA for, or certify, a given rule. With more information and experience, the Agency may conclude that the thresholds defining the categories should themselves be changed. For the time being, however, the Agency believes that the thresholds used in Table 2 are appropriate indicators of whether a rule is unlikely to have a significant impact on a substantial number of small entities.

- i. *Should the Table 2 matrix be applied separately to each type of small entity subject to the rule?*

¹³To overcome the presumption that a rule falling in category 3 will have a significant impact, additional quantitative analysis may be necessary. For examples of types of additional quantitative analysis that could provide further information, see sections IV and VI, and Appendix E, of "EPA Guidelines for Implementing the Regulatory Flexibility Act," prepared by OPPE and dated April 1992.

Where the rule will apply to more than one type of small entity (i.e., small businesses, small governments or small nonprofit organizations), Table 2's matrix should be applied separately to each type of small entity subject to the rule. For example, for a rule that will impose the same (or substantially similar) requirements on small businesses and small governments, the rule's impact on small businesses should be analyzed using an economic criterion appropriate to small businesses, and its impact on small governments should be analyzed using a criterion appropriate to small governments. The results of each analysis should then be fed into the matrix separately. The rule will thus be categorized twice -- once for its impact on small businesses and a second time for its impact on small governments.

Under this approach, it is possible that the rule may be a Category 1 rule with respect to one type of small entity and a Category 2 (or 3) rule with respect to the other. This would be the case, for example, where the rule's impact would be less than 1% of sales for small businesses (Category 1), but 2% of revenues for over 1000 small governments (Category 2). Where a rule falls into more than one category depending on the type of small entity, the rule should be placed in the highest category into which it falls. Thus, in the above example, the rule would be considered a Category 2 rule, and the Agency would approach the decision about whether to prepare a regulatory flexibility analysis or a certification for the rule in accordance with the guidelines for Category 2 rules. The RFA does **not** require that the Agency decide whether to prepare an analysis or a certification based on the rule's impact on the type of small entity most affected by the rule, but EPA has chosen to take this approach to ensure that potentially significant impacts on any one type of small entity are identified and addressed.

Where a rule applies to more than one type of small entity and separate application of the table places the rule in Category 1, one further analytic step is required to categorize the rule: aggregation of the results of the impact analyses on the different types of affected small entities and application of the matrix to the aggregated results. This step is necessary because the table uses absolute numbers as well as percentages to assess whether the rule will impact a substantial number of small entities. The absolute numbers establish a suggested floor and ceiling for what may constitute a substantial number, so that, for example, a rule that impacts over 1000 small entities is identified as potentially affecting a "substantial number" of small entities even if that number represents less than 20% of affected small entities. The Agency chose these absolute numbers as indicative of a substantial number not only with respect to any one type of small entity, but with respect to **all** small entities taken together. Thus, a rule with an impact of 2% of sales, revenues or assests with respect to 334 small businesses, 334 small governments and 334 small nonprofits, where 334 is less than 20% of each type of small entity, would be a Category 1 rule if each type of small entity were looked at separately, but should be a Category 2 rule since more than 1000 small entities may be significantly affected by the rule.

The issue of applying the matrix to each type of small entity may be taken one step further -- that is, should the matrix be applied separately to different kinds of small businesses, small governments or small nonprofits? A rule may apply the same requirements to dry cleaners and autobody shops, but the rule's economic impact may be much greater on one than on the other type of business. As indicated above, it would be appropriate in such a case to analyze the

impact of the rule separately for the two types of business. For purposes of deciding whether to prepare a regulatory flexibility analysis or a certification, however, the impacts of the rule, once assessed for the two types of business, should be aggregated and the aggregates fed into the matrix. If a decision is then made to conduct a regulatory flexibility analysis for the small businesses subject to the rule, the analysis may address the two kinds of businesses separately. Indeed, such a disaggregated analysis is likely to improve the program office's ability to identify ways of tailoring rule requirements to the different characteristics of the affected small businesses.

Any regulatory flexibility analysis or certification prepared for a rule should generally cover the rule's impact on all types of small entities subject to the same (or substantially similar) rule requirements, even if only one type of small entity may be significantly affected in substantial numbers.. The Agency believes that if one type of small entity warrants analysis, it is generally prudent to include all types of affected small entities in the regulatory flexibility analysis and the panel process that accompanies preparation of the initial regulatory flexibility analysis for the rule.

At the same time, any regulatory flexibility analysis prepared for a rule may analyze and address the rule's impact on each type of small entity separately, particularly where the degree and extent of impact varies with the type of small entity. Further, a regulatory flexibility analysis need only explore regulatory alternatives for those types of small entities that would otherwise be significantly impacted by the rule in substantial numbers. The RFA provisions for initial regulatory flexibility analyses require that the Agency discuss any significant regulatory alternatives which "minimize any significant economic impact" of the proposed rule (section 603(c) (emphasis added)). For final rules, the RFA requires that final regulatory flexibility analyses describe "the steps the agency has taken to minimize the significant economic impact on small entities" (section 604(a)(5) (emphasis added)). Thus, the Agency is legally required to describe and address significant regulatory alternatives only with respect to those types of small entities that may be significantly affected by the rule in substantial numbers. As a policy matter, however, program offices should continue to consider and adopt ways of minimizing a rule's burden on any small entities to the extent practicable.

ii. *Are Table 2's listed outcomes mutually exclusive?*

As indicated above, the matrix relates three variables in assigning rules to particular categories. For example, the matrix categorizes a rule based on whether it will have an impact of more than 1% of sales or revenues on less than 100, 100 to 999, or 1000 or more small entities **and** whether the absolute number of small entities so impacted is 20% or more of all affected small entities. In applying the matrix to a rule, it is important to note that the outcomes set forth in the matrix are **not** mutually exclusive. A rule may have an impact of 2% of sales or revenues for 1000 small entities representing 40% of affected small entities (placing it in category 2) **and** 4% of sales or revenues for 500 small entities representing 20% of small entities (placing it in category 3). Where a rule's impact falls into more than one category, the rule should be placed in the highest category.

TABLE 2: Summary of Quantitative Information Used to Identify Applicable Categories¹

Quantitative Criteria			Regulatory Process Category ²
Economic Impact Condition (based on preferred criteria from Table 1)	Number of Small Entities Experiencing Economic Impact Condition	Number of Small Entities Experiencing Economic Impact Condition as a Percentage of All Affected Small Entities	
Less than 1% for all affected small entities	Any number	Any percent	Category 1
1% or greater for one or more small entities ³	Fewer than 100	Any percent	Category 1
	100 to 999	Less than 20%	Category 1
	100 to 999	20% or more	Category 2
	1000 or more ⁴	Any percent	Category 2
3% or greater for one or more small entities	Fewer than 100	Any percent	Category 1
	100 to 999	Less than 20%	Category 2
	100 to 999	20% or more	Category 3
	1000 or more ⁴	Any percent	Category 3

¹ Nothing in this table on applying quantitative measures of economic impacts and enumerating the number of impacted small entities should be interpreted as indicating that the certification decision is strictly or solely based upon application of the above quantitative steps. Additional information and other factors may be relevant in deciding whether to prepare a regulatory flexibility analysis or certify under the RFA.

² There may be cases where the extent of the impact (measured in quantitative or qualitative terms) is particularly severe, even though the number of affected small entities totals fewer than 100 or 20% of all affected small entities. In such cases, the lead office should consider placing the rule in a higher category than would otherwise be applicable.

³ For purposes of applying this portion of the table, the number of small entities that will experience an impact of 1% to 3% must be aggregated with the number of small entities that will experience an impact of 3% or greater. The total number of small entities that will experience an impact of 1% or greater must be used here in order to determine whether the number of small entities so impacted is large enough to warrant preparation of a regulatory flexibility analysis.

⁴ As the number of small entities that will be affected by a rule by more than 1% of sales or revenues approaches 1000 in number, the substantial number criteria of 20% of affected small entities may become less relevant in determining whether a regulatory flexibility analysis or a certification should be prepared.

d. After applying the matrix, what then?

As noted above, the thresholds and criteria set forth by this guidance cannot be applied mechanistically. Additional information and other factors may be relevant in deciding whether or not to certify a rule under the RFA.

I. *Would an alternative definition of "substantial number" be appropriate?*

When application of the matrix indicates that a rule will not impact a "substantial number" of small entities, it is appropriate for the program office to consider whether alternative approaches to defining "substantial number" should apply for one of the following reasons:

- Where the extent of the impacts, measured in economic or non-economic terms, would be of sufficient magnitude (e.g., potential collapse of a viable regionally-concentrated fraction of an industrial sector) to warrant using either a smaller absolute number (i.e., a figure lower than 100) or a smaller fraction of small entities (i.e., a figure lower than 20%).
- Where the size and distribution of entities within the industry, the distribution of revenues, market share, etc., suggest an alternative definition for businesses. In such cases, it may not be possible or appropriate to determine whether a "substantial number" will be affected until after collecting the data necessary to prepare an IRFA or FRFA and analyzing the data for this purpose.

ii. *Should relative impacts be analyzed?*

Comparing a rule's impacts on small entities versus large entities (i.e., a rule's disproportionate impact on small entities) may be one analytical means of providing additional insight into whether a rule will have a "significant impact" on a "substantial number" of small entities. Analytical tests and criteria for making relative comparisons are listed in section V of "EPA Guidelines for Implementing the Regulatory Flexibility Act," prepared by OPPE and dated April 1992.

iii. *Are there other qualitative considerations relevant at this stage?*

Qualitative information may also be factored into this phase of determining whether a rule will not have a significant impact on a substantial number of small entities. Qualitative assessment of the impacts on small entities ensures consideration of legitimate non-quantitative factors that may or may not be supported through data. Qualitative analysis can take on the appearance of a quantitative analysis, such as when the program office uses its judgement to make use of related summary data or "model" financial data in the absence of more detailed information. For example, where data cannot be obtained for the particular type of small entity subject to the rule, the program may choose to use quantitative information on another type of small entities whose behavior and financial characteristics are similar to those subject to the rule. Another example might entail the creation of baseline financial characteristics for a set of small entities drawing upon quantitative information available on larger entities in the same industrial or governmental sector. General patterns of comparison between larger and smaller entities may be drawn upon so as to infer the small entities' financial characteristics. In general, where quantitative information is sought, the goal is to obtain the type of data that allows for the most reliable form of quantitative analysis to be used by the program office. But where data limitations persist, adoption of creative reliable alternatives is encouraged.

iv. *Should the screening analysis be reviewed within the Agency?*

The Assistant Administrator of the office preparing a screening analysis is responsible for ensuring the integrity and validity of the analysis. Among the mechanisms that the AA (and workgroup chair for the rule) may rely upon in preparing an analysis are review by workgroup members and consultation with the Division of Economy and the Environment in OPPE's Office of Economy and the Environment, the Small Business Advocacy Chairperson, the Small Business Ombudsman and/or the Small Community Coordinator, as appropriate.

IV. FULFILLING THE RFA'S ANALYTICAL REQUIREMENTS

Once a determination is made regarding whether to prepare a regulatory flexibility analysis or a certification for a proposed or final rule, the program office must fulfill the applicable RFA analytical requirement. Since the screening process itself entails qualitative and quantitative analysis, it will provide the basis for certifications of no significant impact and much

-- but by no means all -- of the information necessary for preparing IRFAs and FRFAs. This section of the guidance discusses how to fulfill the requirements for certifications, IRFAs and FRFAs.

A. Certification of No Significant Impact

For any proposed or final rule the Agency intends to certify as having no significant impact on a substantial number of small entities, the following statement must be included in the Regulatory Flexibility section of the rule's preamble: "I certify [or 'The Agency certifies'] that the rule will not have a significant economic impact on a substantial number of small entities."¹⁴ That statement must be followed by at least a summary of the factual basis for the certification. If only a summary is provided, a full explanation must be provided elsewhere in the rulemaking record and the summary should reference that explanation. To keep Federal Register notices from becoming too long and unwieldy, program offices should include only summaries where the full explanation is lengthy.

The factual basis for a certification will vary with the particular rule. In the case of rules that will impact **no** small entities or that will have **no adverse** impact on small entities, the factual statement need only make that point and summarize or reference the analysis that supports it. In the case of other rules being certified, the factual statement should consist of a summary of the Agency's impact findings based on the results of the screening analysis described above. The factual statement should **not** cite to this guidance for substantiation that the rule's estimated impacts will not be significant nor fall on a substantial number of small entities. While the Agency considers the thresholds contained in this guidance to be generally appropriate indicators of "significant impact" and a "substantial number," they are not talismanic. The program office and Agency as a whole must still exercise judgment in deciding whether to certify a rule and then explain that judgment in light of the specific circumstances of the rule. Any explanation of a certification should thus state what the impacts are and indicate that the Agency considers those impacts insignificant. For example, for a rule with an impact of less than 1% for a relatively small number of small entities, the Regulatory Flexibility section of the preamble should so state and conclude (unless a contrary determination has been made in light of circumstances unique to the rule) that the Agency does not consider such an impact to amount to a "significant impact on a substantial number of small entities."

As noted earlier, for any rule that will have some impact on some number of small entities, but not a "significant impact" on a "substantial number" of such entities, the Agency's

¹⁴As noted previously, the Agency official authorized to sign a rule generally is also authorized to certify the rule under the RFA, so use of the "I certify" language is appropriate. There are instances, however, where Agency officials below the Office Director (OD) level are authorized to sign a rule. However, officials below the OD level are **not** authorized to sign certifications. In such instances, the phrase "I certify" should be replaced with "the Agency certifies," the signed certification should be placed in the docket, and the preamble should state that the signed certification is available in the docket for the rulemaking.

policy is to assess and minimize those impacts to the extent possible, even though preparation of an IRFA or FRFA is not required. In keeping with that policy, the program office should also include in the Regulatory Flexibility section of the preamble a discussion or summary of the ways in which the rule has been developed or designed to minimize impacts on small entities, or a cross-reference to the part of the preamble or rulemaking document that contains such a discussion.

B. Initial Regulatory Flexibility Analysis

For any proposed rule subject to the RFA that the Agency does **not** certify as having no significant impact, an IRFA must be prepared.¹⁵ The RFA spells out what IRFAs must contain, and the statutory background section of this chapter sets forth the required elements.

As indicated in the statutory background section, several IRFA requirements will generally be met by other portions of the proposed rulemaking preamble, so cross-references to those portions will suffice. Other IRFA requirements will be fulfilled by summarizing and referencing the information and analysis developed by the screening process. At the same time, a critical IRFA element typically will not be covered by other portions of the rulemaking preamble or the screening analysis. For that element, the Agency must identify and describe "any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities." The RFA lists examples of "significant alternatives" that agencies should explore and discuss in the IRFA. This portion of the IRFA is **not** primarily an exercise in economic analysis but one of program design and scope. Program offices should therefore anticipate that policy-making staff and officials will have a large role in the preparation of this section.

The IRFA should be summarized in the Regulatory Flexibility section of the proposed rule's preamble. The summary of the IRFA should note in particular the ways in which the Agency designed the proposed rule to reduce burdens on small entities. The full IRFA should be placed in the rulemaking docket and the preamble summary should indicate where the IRFA can be found.

Besides summarizing the IRFA, the Regulatory Flexibility section of the preamble should also describe or summarize the actions the Agency took to involve small entities in the rule's development, including outreach to small entity stakeholders and convening of a small business advocacy review panel. Including this information in the proposed rule's preamble will simplify preparation of the report the Agency must prepare for Congress and the General Accounting

¹⁵In preparing an IRFA or FRFA, the program office need not and should not attempt to establish or "certify" that the proposed or final rule will have a significant impact on a substantial number of small entities. The RFA requires an agency to make a finding of insignificance where it does **not** prepare an IRFA or FRFA; the RFA does **not** require an agency to make a finding of "significance" where it prepares an IRFA or FRFA. Put another way, where an agency prepares an IRFA or FRFA, it need not characterize the impact of the rule, only analyze it.

Office on the final rule.

C. Final Regulatory Flexibility Analysis

For any final rule subject to the RFA that the Agency does **not** certify as having no significant impact, a FRFA must be prepared. The RFA spells out what FRFAs must contain, and SBREFA's amendments of the RFA strengthened several of the analytical elements of a FRFA. The statutory background section of this guidance sets forth the required elements of a FRFA.

As indicated in the statutory background section, several requirements for a FRFA will generally be met by other portions of the final rulemaking preamble, so cross-references to those portions will suffice. Other FRFA requirements will be fulfilled by summarizing and referencing the information and analysis developed by the screening process. To the extent that the final rule does not differ from the proposed rule and the Agency obtained little or no additional information relevant to the regulatory flexibility analysis of the rule, the FRFA can rely on cross-references to still-current sections of the IRFA.

Similar to the APA requirement to respond to comments on a proposed rule, the RFA requires that a FRFA summarize the significant issues raised by public comments on the IRFA, summarize the agency's assessment of such issues and describe any changes the agency made in response to the comments. To the extent that the program office prepares for a rule a single response-to-comments document that fulfills the requirements for a FRFA, it may rely on and cross-reference that document in the FRFA.

As with the IRFA, probably the most critical component of the FRFA is the requirement that an agency explain the "factual, policy and legal reasons" it selected the regulatory approach promulgated in the final rule and why it rejected "each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities." While the RFA does not require that an agency necessarily minimize regulatory burdens on small entities, it does require that the agency describe the "steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes." Both the requirements to explain the agency's choice of regulatory approach and describe what the agency has done to minimize any significant impact make it incumbent on the Agency to carefully consider ways of reducing significant impacts on small entities in reaching final decisions on a rule and to document that consideration. To the extent that both requirements are met by the main body of the preamble of the final rule, the FRFA may cross-reference it.

The FRFA should be summarized in the Regulatory Flexibility section of the final rule's preamble. The summary of the FRFA should note in particular the ways in which the Agency reduced the impact of the final rule on small entities to the extent feasible. The full FRFA must be placed in the rulemaking docket and the preamble summary should indicate where the FRFA can be found.

Besides summarizing the FRFA, the Regulatory Flexibility section of the final rule's preamble should describe the actions the Agency took to ensure that small entities had a meaningful opportunity to comment on the rule. That section should also reference the counterpart section of the proposed rule's preamble for a description of the Small Business Advocacy Review Panel convened for the rule (if applicable). Including this information and reference regarding the Agency's outreach efforts in the final rule's preamble will facilitate preparation of the report the Agency must prepare for submitting the rule to Congress and the General Accounting Office under the congressional review provisions of SBREFA.

Chapter 2

Identifying Small Entity Representatives

Section	Subject	Page
I.	Introduction	1
II.	Statutory Background	1
III.	Coordinating Organization	2
IV.	Recommended Actions	2
V.	Points of Contact	4

I. INTRODUCTION

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) amended the Regulatory Flexibility Act (RFA) to bolster the RFA's requirements that agencies ensure that small entities (i.e., small businesses, small governments and small nonprofit organizations) have a meaningful opportunity to participate in the development of rules that will have a significant economic impact on a substantial number of small entities. Detailed below is a strategy outlining how program offices in EPA can identify representatives of small entities that may be affected by Agency rulemakings. In particular, the strategy describes the respective roles of the program offices and the Small Business Ombudsman Program (SBOP), the Office of Regional Operations and State/Local Relations' (OROSLER's) State/Local Relations Division, and the Office of Communications, Education and Public Affairs' (OCEPA's) Public Liaison Division in developing, distributing and coordinating lists of potential small entity "contacts."

II. STATUTORY BACKGROUND

As explained in detail in Chapter 1, the RFA has long required that an agency prepare a regulatory flexibility analysis for any notice-and-comment rule, **unless** the agency certifies that the rule will **not** have a significant economic impact on a substantial number of small entities. The RFA has also required that an agency "assure that small entities have been given an opportunity to participate in the rulemaking process" for any rule "which will have a significant economic impact on a substantial number of small entities" (current RFA section 609(a)). Any rule requiring a regulatory flexibility analysis thus requires agency outreach efforts, as well. The agency is to assure small entity participation through the "reasonable use of techniques such as"

those listed in RFA section 609(a) as amended by SBREFA. The list includes:

- use of computer networks to solicit and receive comments;
- publication of the notice of proposed rulemaking in publications likely to be obtained by small entities;
- direct notification of interested small entities;
- conduct of open conferences or public hearings concerning the rule for small entities;
- inclusion in an advance notice of proposed rulemaking, if issued, of a statement that the proposed rule may have a significant economic effect on a substantial number of small entities; and
- the adoption or modification of agency procedural rules to reduce the cost and complexity of participation in the rulemaking for small entities.

SBREFA strengthened the RFA's outreach provisions in two principal ways. First, the RFA now requires EPA to convene "Small Business Advocacy Review Panels" prior to proposing a rule, **unless** the EPA certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. As described in detail in Chapter 3, the panels are required to consult with representatives of small entities that will be subject to the rule. Second, the amended RFA allows small entities to sue agencies in court for failure to comply with specified RFA provisions, including section 609(a), which, as noted above, requires agencies to "assure" that small entities have an opportunity to participate in rulemakings that will have a significant economic impact on a substantial number of small entities.

III. COORDINATING ORGANIZATION

EPA's SBO, located in OPPE's Office of Regulatory Management and Information (ORMI), will coordinate and provide primary support and assistance to the program offices at EPA Headquarters in their outreach activities to small entities under the RFA as amended by SBREFA. Additional support and assistance will be available from OROSLR's State/Local Relations Division and the OCEPA's Public Liaison Division.

Assistance will include supporting the distribution of information on the SBREFA, the RFA as amended and relevant issues to small entity contacts, as well as helping to coordinate and maintain a comprehensive list of small entity contacts for use by the individual program offices. Points of contact and telephone numbers within EPA's SBO, OROSLR, and OCEPA are provided below.

IV. RECOMMENDED ACTIONS

- A. The SBO will distribute information on SBREFA to the individuals and organizations on its small entities contact list. SBO stays in active communication with these contacts on an ongoing basis.

The SBO maintains and continually updates a master list of key small entity contacts, which will be made accessible to the program offices through the EPA computer network.

- ▶ National small entity trade association executives and contact persons
- ▶ Contacts for the State Section 507 Program, including the Small Business Ombudsman, Small Business Assistance Program, and the Compliance Advisory Panels
- ▶ EPA Regional Small Business Liaisons

B. The EPA SBO will communicate with the Small Business Administration (SBA) to review their lists of contacts, and revise such lists, as appropriate, to ensure they are consistent. In addition, the SBO will coordinate review of this "revised" list with the EPA Program Office Workgroup Chairpersons, or their designees, to supplement this list as needed, based on the program offices historical and planned outreach efforts.

C. Through the efforts of the EPA SBO, the Section 507 Program State Small Business Ombudsman and Technical Assistance Programs will be strongly encouraged to maintain a similar contact list for their states, and to share this list with the EPA SBO on an as-needed basis.

D. OROSLR and OCEPA will help support and provide assistance to the program offices in their outreach to small entities. Assistance will include:

- ▶ supporting the distribution of information on SBREFA and relevant issues to their small entities contacts
- ▶ helping to coordinate, maintain, and update a comprehensive list of small entities contacts for use by the EPA program offices.

E. Each program office at EPA Headquarters Office should develop and maintain a comprehensive contact list of small entity representatives, keyed to their program area of responsibility. For example:

- ▶ small business trade associations; and
- ▶ organizations representing townships, counties and municipalities, and decision-making individuals within these organizations (public and private non-profit)

This contact list should be utilized to help identify knowledgeable individuals who may serve as small entity contacts for Agency rulemakings affecting small entities.

F. For any rule for which the Agency prepares a regulatory flexibility analysis (see Chapter 1), the program office responsible for developing the rule should keep a record of their outreach efforts and include that record in the rulemaking docket by the time the rule is promulgated, for purposes of judicial review.

G. Each program office should maintain a list to track their regulatory actions which will, or are likely to, require a regulatory flexibility analysis under the RFA. The list should include at least the items listed below.

- ▶ Title of Action
- ▶ SAN No.
- ▶ Level of Action/Tier;
- ▶ Name, Telephone/Fax Nos. of Principal Contact
- ▶ Deadlines (proposed and final)
- ▶ Current Schedule (proposed and final)
- ▶ SIC Codes/Small Entities impacted
- ▶ Small Entity Rep(s); Name(s), Organization(s), and Phone/Fax No(s)

V. POINTS OF CONTACT

- A. The primary point of contact is the Small Business Ombudsman Program.

EPA Small Business Ombudsman Program		
Karen V. Brown, EPA Small Business Ombudsman telephone: (703) 305-5938, fax: (703) 305-6442		
Individual	Telephone Number	Media/Regulatory Speciality
Robert Rose	(703) 305-5511	Clean Air Act, and other
James Malcolm	(703) 305-7015	Toxic Substances and Hazardous Wastes
Larry Tessier	(703) 305-7645	Asbestos, Radon, and Lead
Arnold Medbery	(703) 305-5171	Clean Air Act, Water, Asbestos
Thomas Nakley	(703) 305-5046	Clean Water Act

- B. Also providing guidance assistance and support in outreach to small entities under SBREFA are the two programs involved with small governments and small communities, and non-profit organizations:

Small Governments and Small Communities

Michele Hiller, Director
 State/Local Relations Division (1502)
 Office of Regional Operations and State/Local Relations (OROSLR)
 (202) 260-3870

Non-profit Organizations

Amy Dewey, Acting Director
 Public Liaison Division (1702)
 Office of Communications, Education and Public Affairs (OCEPA)
 (202) 260-4454

Chapter 3

Small Business Advocacy Review Panels

Section	Subject	Page
I.	Introduction	1
II.	Statutory Background	2
III.	Overview of Suggested Panel Process	4
IV.	Preliminary Notification	5
V.	Formal Notification	6
VI.	Panel Review	9

I. INTRODUCTION

As explained in detail in Chapter 1, SBREFA amended the RFA to, among other things, require EPA to convene a "Small Business Advocacy Review Panel" for any proposed rule for which the Agency prepares an initial regulatory flexibility analysis. The RFA requires that an agency prepare an initial regulatory flexibility analysis for any proposed rule, **unless** the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities." Accordingly, if the Agency does **not** certify a proposed rule under the RFA, it must convene a Small Business Advocacy Review Panel. Although the statutory name for the panel refers only to small business, panels are to solicit and consider the concerns of small governmental jurisdictions and small nonprofit organizations, as well as small businesses, depending on which types of "small entity" are affected by the rule.

This document sets forth a step-by-step approach to implementing the Small Business Advocacy Review Panel requirement. While SBREFA establishes the basic outlines of the panel process (see statutory background section below), it also leaves to agency discretion many details of that process, including when to convene a panel prior to proposing a rule. EPA has exercised that discretion to develop a suggested process that will typically involve small entity representatives early in the rule's development when their comments and insights can inform the Agency's thinking about fundamental issues of rule design and scope, as well as more specific issues posed by the particular regulatory program at issue. In many respects, the suggested guidance goes beyond what is legally required. At the same time, EPA recognizes the need for flexibility in implementing this guidance. Many rulemakings subject to the panel requirement

may be so far along that the panel process must take place later in the rulemaking than this guidance suggests. The process is also new. EPA anticipates learning from its experience implementing the process and revising this guidance as appropriate.

The suggested panel process is divided into several parts. It may not be necessary to complete each part of the process if, during the course of rule development, it is determined that the rule will not have a significant impact on a substantial number of small entities. However, even where an action will not have a significant impact on a substantial number of small entities, but will have an impact on one or more small entities, it is important that the Agency engage in consultation with the relevant small entity community.

II. STATUTORY BACKGROUND

Since the RFA was enacted in 1980, section 609 has required agencies to facilitate small entities' participation in rulemakings that will have a significant economic impact on a substantial number of small entities (see Chapter 2 for further discussion of general outreach requirement). With SBREFA, section 609 has been expanded to require EPA and the Occupational Health and Safety Administration (OSHA) to convene Small Business Advocacy Review Panels to ensure that small entity representatives are involved in the development of EPA and OSHA proposed rules.

Under section 609(b) as added by SBREFA, EPA must convene a Small Business Advocacy Review Panel for any rule for which the Agency prepares an initial regulatory flexibility analysis. If EPA certifies that the proposed rule will not have a significant impact on a substantial number of small entities, it need not convene a panel. (Section 609(c) authorizes EPA to convene a panel for a rule that the Agency intends to certify, but that the Agency believes may have "a greater than de minimis impact on substantial number of small entities.") Section 609(b) requires that the panel process occur **before** publication of the initial regulatory flexibility analysis, which must be published at the same time the proposed rule is published, except in cases of emergency. Accordingly, panels must generally be convened **before** the rule is proposed.

Section 609(b) establishes the following framework for the panel process:

- For any rule subject to the panel requirement, the Agency is to notify the Chief Counsel for Advocacy of the Small Business Administration (SBA) and provide the Chief Counsel with information about the potential impact of the rule on small entities and the type of small entities likely to be affected.
- The Chief Counsel has 15 days from receiving notification of a rule to identify individuals representative of the small entities likely to be affected by the rule.
- EPA is to convene a review panel consisting **only** of full-time federal employees, including representatives of the Agency office responsible for developing the rule, the

Office of Management and Budgets' Office of Information and Regulatory Affairs (OIRA), and the SBA Chief Counsel for Advocacy.

- The panel is to review any material the Agency has prepared in connection with the RFA, including any draft proposed rule, and to collect the advice and recommendations of small entity representatives selected by the Agency, after consultation with the Chief Counsel for Advocacy, on issues related to specified elements of the initial regulatory flexibility analysis for the proposed rule under development. The specified elements are:
 - a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
 - a description of projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the record or report;
 - an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule; and
 - a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities (see Chapter 1 for examples of potential alternatives).
- Not later than 60 days after EPA convenes the panel, the panel is to report on the comments of the small entity representatives and the panel's findings with regard to the issues related to the initial regulatory flexibility analysis elements listed above. The panel report is to be included in the rulemaking record.
- In light of the panel report, the Agency is to modify, where appropriate, the proposed rule, the initial regulatory flexibility analysis or the decision on whether an initial analysis is required.

The Chief Counsel for Advocacy may waive the panel requirement for a rule if the Chief Counsel finds that convening a panel would not advance the effective participation of small entities in the rulemaking process. (Note, however that the waiver applies only to the requirement to convene a panel; it does not relieve the Agency from notifying the Chief Counsel of the rule or the Chief Counsel from identifying small entity representatives.) Factors the Chief Counsel is to consider include the extent to which the agency has already consulted with small entity representatives and taken their concerns into account; "special circumstances necessitating prompt issuance of the rule;" and whether the panel process would provide the small entity representatives involved in the process a competitive advantage over other small entities. Before granting the waiver, the Chief Counsel must consult with OIRA and the small entity

representatives the Chief Counsel identified after receiving notification of the rule. The Chief Counsel must also include a written explanation of the waiver decision in the rulemaking record.

Under SBREFA section 244(b), panels are to be chaired by a Small Business Advocacy Chairperson designated by the Administrator. The Chairperson is to be responsible for implementing the review panel process and to act as permanent chair of the Agency's review panels. Administrator Browner appointed Tom Kelly, Director of the Office of Regulatory Planning and Management of OPPE, to serve as the Agency's first Small Business Advocacy Chairperson.

III. OVERVIEW OF SUGGESTED PANEL PROCESS

The first steps of the process are actually designed to determine whether a panel must be convened for a particular rule. As noted above, unless the Agency certifies that the rule will not have a significant economic impact on a substantial number of small entities, a panel must be convened. Accordingly, the program office responsible for the rule should identify the rule's potential impact on small entities as soon as possible, and consider ways of structuring the rule to avoid any undue burden on small entities. To the extent the program office is successful in designing the rule to avoid any significant impact on a substantial number of small entities, a panel need not be convened.

If the rule may have a significant impact on a substantial number of small entities, the program office should proceed with the next steps of the panel process, which include identifying and initiating discussions with representatives of small entities potentially affected by the rule, and providing early, informal notification of the rule to the Chief Counsel for Advocacy through the Agency's Small Business Advocacy Chairperson. (The Chief Counsel's Office may also be helpful in identifying small entity representatives for early consultation.) This part of the process should typically occur before the rule has been drafted, to make it easier for small entity suggestions to be incorporated into the rule's design. Indeed, early discussions with small entity representatives and the Chief Counsel's Office may bring to light other ways of structuring the rule to avoid any significant impact on substantial numbers of small entities, in which case a panel need not be convened.

If, on the other hand, such discussions or other information (including the screening analysis described in Chapter 1) suggest that a panel should be convened, the program office, through its Steering Committee Representative, should request that the Agency's Small Business Advocacy Chairperson (SBAC) provide the Chief Counsel for Advocacy with formal notification of the rule. Formal notification does **not** commit the Agency to convening a panel. The program office may still learn as a result of further consultations with small entity representatives and the Chief Counsel's Office or further analysis that the rule will not have a significant economic impact on a substantial number of small entities, and thus that neither an initial regulatory flexibility analysis nor a panel is required.

After receiving the Chief Counsel's official suggestions for small entity representatives, the program office should select the final slate of representatives to be contacted for the panel report. (Presumably, the representatives will be the same as, or at least include, any of the small entity representatives the program office has previously contacted.) The program office should then collect the representatives' advice and recommendations for inclusion in the report (the small entity representatives are **not** members of the panel itself). Typically, this stage of the process will also take place before the rule is drafted, but an outline describing the important components of the rule and any significant alternative approaches should be provided to the representatives.

To the extent the representatives' comments and any other information confirm that the rule is likely to have impacts warranting preparation of an initial regulatory flexibility analysis, the program office should prepare a draft panel report containing the representatives' comments and the findings required by section 609(b). The SBAC will then convene the panel by sending the draft panel report to the panel members for their review. The panel members will confer with one another and the small entity representatives as needed to prepare a final report. The final report will be made available to the public and considered by Agency managers in making final decisions about the the scope and terms of the proposed rule.

Waivers of the panel requirement will only be considered in exceptional circumstances (e.g., when a rule is subject to a near-term legal deadline) or where the Agency has already engaged in extensive outreach to representatives of potentially affected small entities. All waiver requests will be submitted through the Agency SBAC.

IV. PRELIMINARY NOTIFICATION

[**NOTE:** An important resource for the panel process will be the lists of potential small entity representatives that Program Offices develop under Chapter 2 to support their rulemaking activities generally. Such lists will identify sources of potential representatives of small entities actually or potentially affected by the Program Office's regulatory programs (e.g., small business trade associations, small governmental jurisdictions and small nonprofit organizations).]

A. For each rule, or group of related rules, the Program Office identifies as early as possible what types of small entities are likely to be adversely affected by the rule, and what those adverse impacts are apt to be (to the extent feasible at this early stage).

- If it appears that the rule most likely will not have a significant adverse impact on a substantial number of small entities, the Program Office should nonetheless conduct whatever outreach is necessary to address the small-entity impacts that do exist and to gather the information necessary for a certification of "no significant impact". If the outreach reveals that the rule may in fact have a significant impact

on a substantial number of small entities, the Program Office should proceed with the process outlined below.

- If it appears that the rule may have a significant adverse impact on a substantial number of small entities, the Program Office should consider whether and how the rule could be structured to avoid significant impacts on a substantial number of small entities. For this purpose, the Program Office should consider consulting with the SBAC, EPA's Small Business Ombudsman (SBO) or other relevant Agency office (e.g., Office of Regional Operations and State/Local Relations (OROSLER)) and appropriate small entity representatives identified by means of the lists developed under Chapter 2 or by the SBAC, SBO or OROSLER. If it continues to appear that the rule may have significant impacts, proceed with the steps outlined below.

B. To the extent it appears that the rule may have significant impacts on small entities, the Program Office's Steering Committee Representative (SC Rep) requests that the Agency SBAC give the SBA Chief Counsel for Advocacy (hereinafter "SBA Chief Counsel") preliminary notification that EPA is developing a rule that may have significant small entity impacts, and that a formal request to identify small entity representatives is likely.¹⁶

- At this time, the Agency SBAC will also provide the SBA Chief Counsel with a Program Office staff contact (normally this will be the workgroup chair), and will ask the SBA Chief Counsel for an SBA staff contact.
- Once this preliminary notification has been made, the Program Office staff is free to confer directly with SBA staff regarding appropriate small entity representatives.

V. FORMAL NOTIFICATION

A. To the extent it continues to appear that the rule may have significant impacts on small entities, the Program Office SC Rep requests that the Agency SBAC provide

¹⁶If the Program Office is interested in pursuing a waiver of the panel requirement for the rule, the Program Office SC Rep should consult with the Agency SBAC, who will submit any waiver requests to the SBA Chief Counsel. If the Agency decides to request a waiver, the Program Office and SBAC will still need to complete the formal notification step of the process as outlined below. The SBAC will also informally notify the SBA Chief Counsel of the Agency's intent to request a waiver before formally requesting it. If the Chief Counsel grants the waiver, the Program Office may skip the remaining steps of the panel process, but should conduct as much outreach as time permits or as appropriate under the circumstances.

formal, written notification to the SBA Chief Counsel that a rule is being developed that may have a significant adverse impact on a substantial number of small entities. Formal notification triggers the Chief Counsel's obligation to identify small entity representatives with 15 days of the notification's receipt.

- The Program Office should provide the SBAC with the following information for purposes of the notification:
 - a description of the problem the rule is trying to solve;
 - a list of the types of small entities likely to be affected;
 - a list of potential small-entity representatives already identified, if any; and
 - any other material that has already been shared with small-entity representatives.
 - The notice will emphasize that the request to identify small entity representatives **does not represent an EPA finding that the rule will have a significant impact on a substantial number of small entities, nor does it commit EPA to preparing a formal regulatory flexibility analysis or convening a formal advocacy review panel.** The small entity representatives can provide input to help the Agency ultimately determine if either of these activities are actually required, and offer ideas to help minimize the impact to the point that the regulatory flexibility analysis and panel requirements are no longer triggered.
- B. Through the Agency SBAC, the Program Office receives a list of suggested small entity representatives from the SBA Chief Counsel and, after appropriate consultation with SBA staff, decides on the official list of small entity representatives**
- While the RFA authorizes the Agency to select the small entity representatives for the panel process, the small entity representatives identified by the SBA Chief Counsel generally should be included. Before any SBA-suggested representative is not included on the official list, the Program Office SC Rep should consult with the Agency SBAC.
 - The Program Office can include on the official list entities not suggested by the Chief Counsel, but it would be wise to inform SBA staff so they will know who all the representatives are. If possible, it is desirable to reach a consensus with the Chief Counsel on the universe of small-entity representatives.
- C. The Program Office conducts outreach to official small entity representatives.**
- The small entity representatives must be provided with enough information about the rule for them to be able to judge the likely impacts of the rulemaking on small entities. Outreach materials could (but need not) include any draft of the rule or preamble text, but such materials may not be available because the panel process

will normally be conducted early in the rulemaking, when it is most effective.

- **Each** small entity representative must be solicited for information, advice and recommendations on issues relating to the elements of an initial regulatory flexibility analysis listed in the "Statutory Background" section above.¹⁷
- The small-entity representatives should be encouraged to put their comments and suggestions in writing.
- Program staff should keep detailed records of the small entity representatives' participation for later use in developing the rule and any regulatory flexibility analysis or certification for the rule (since the outreach process may lead to, and help substantiate, a determination that the rule will **not** have a significant impact on a substantial number of small entities), and as documentation of the Agency's outreach efforts.
- Any materials provided to, or received from, small entity representatives should be included in the docket for the rulemaking at the earliest practicable time so that all parties interested in the rulemaking will have access to those materials.
- If the outreach process indicates that there will be "no significant adverse impact on a substantial number of small entities", the Program Office should develop a formal certification for the rule and skip the remaining steps of the panel process. (Refer to **Chapter 3: Analytical Requirements of the Regulatory Flexibility Act** for further guidance on preparing the certification statement.) Otherwise, proceed with the remaining steps of the process.

D. The Program Office prepares a draft report for the Panel.

- The draft report should include the following:
 - a description of the outreach effort conducted by the Program Office;
 - a summary of the information, comments and advice received from each small entity representative in response to the outreach solicitation described above;
 - draft findings as to issues related to the elements of the initial regulatory flexibility analysis listed in the "Statutory Background" section; and
 - as an appendix, copies of the written comments submitted by the small entity representatives to the Agency.

¹⁷Small entity representatives can be consulted individually, particularly since the RFA requires that the panel collect the advice and recommendations of "each" representative. If, however, the program office chooses to consult with small entity representatives as a group or in a group setting, issues under the Federal Advisory Committee Act (FACA) may be raised and OGC should be consulted.

- The draft report will **not** contain a discussion of the regulatory option or options actually selected by the Agency, since the report will normally be prepared before such decisions are made, in order to inform those decisions.

VI. PANEL REVIEW

A. At the request of the Program Office SC Rep, the Agency SBAC Convenes the Advocacy Review Panel

- The panel will be chaired by the Agency SBAC, with the Workgroup Chair (or designated alternate) for the rule serving as the Panel Co-Chair. The other two panel members will be a representative of the SBA Chief Counsel and a representative of OMB/OIRA.
- The panel will be convened upon distribution of the draft panel report (described above) by the Agency SBAC to the panel members. The draft report will be used as a vehicle for initiating review.
- The panel is to review any RFA-related materials and any draft proposed rule, if those materials have been prepared by the time the panel convenes. Since panels will typically convene before a draft rule is prepared, the panel members should be provided with an outline describing the important components of the rule and any significant regulatory alternatives identified by the Agency.
- The product of the panel will be a final report based on its deliberations. The panel need not reach consensus in order to issue a final report; the views of each of the members can simply be reflected in that report.
- The final report will **not** contain a discussion of the option or options actually selected by the Agency, since the report will normally be prepared before such decisions are made, in order to inform those decisions.
- The panel has 60 days from the date it is convened to produce its official final report. The panel is not required to take the full 60 days, and should issue its report as soon as possible, to provide timely input to the development of the proposed rule.
- It is expected that the panel process will normally be concluded well in advance of Workgroup Closure (or equivalent stage for Tier 3 rules), in order to be most useful to the development of the proposed rule.

B. The Agency considers the results of the Panel report as it develops the proposed rule and Initial Regulatory Flexibility Analysis

- The Panel report will be considered by the Agency in selecting proposed regulatory options to address small entity concerns.
- The panel report should be placed in the docket for the rulemaking so that it will be accessible to all parties interested in the rulemaking.
- After the Panel report is issued, the Agency should generally continue its outreach efforts as the proposed rule is prepared.
- The results of the outreach and panel process, and their role in the Agency's deliberations, should be documented in the initial regulatory flexibility analysis prepared for the rule and briefly summarized in the Regulatory Flexibility Section of the preamble of the proposed rule.

Chapter 4

Development and Distribution of SBREFA Compliance Guides

Section	Subject	Page
I.	EPA's Approach to Compliance Guides	1
II.	SBREFA Compliance Guide Template	6

I. EPA'S APPROACH TO COMPLIANCE GUIDES

A. What does SBREFA require?

1. When the Agency prepares a regulatory flexibility analysis for a final rule, SBREFA Section 212 also requires the Agency to:
 - a. designate one or more publications regarding such a rule or group of rules as small entity compliance guides;
 - b. explain in the guide actions a small entity must take to comply with a rule or group of rules; and
 - c. distribute the guides to small entities through "comprehensive sources of information."
2. While compliance guides are not themselves judicially reviewable, they may be considered as evidence of the reasonableness or appropriateness of any penalties or damages in any civil or administrative action against a small entity. Accordingly, the statute gives us broad discretion with regard to implementation of these requirements for designation, development and distribution of the guides. The sections that follow describe how the Agency has chosen to exercise this discretion, the specifics of which may not necessarily be required by SBREFA. As we gain experience, we may issue additional guidance.

B. What is the goal in writing a compliance guide?

The primary goal of the guide is to help small entities-- whether they are small

businesses, communities or non-profits-- to comply with the regulation. You should therefore write your guide with your audience in mind and recognize that this segment of our regulated community may have trouble with standard government writing styles. We suggest that you write in plain and simple language insofar as possible. (While small entities are the primary audience for the guides, some of the compliance information may also be applicable to large entities and you may choose to present these similarities/differences as you develop your guide).

C. Who participates in the development of the Guides?

1. The lead rule-writing office is responsible for developing the rule-specific compliance guide as part of the rulemaking process.
2. The regulatory development workgroup, as well as representatives from OECA, OGC, OSBO, OPPT's Pollution Prevention Division, and regional offices can also provide assistance/support, or develop sections of the guide, as appropriate. If your regulatory development workgroup is not represented by the appropriate offices, you should work through your Steering Committee representative to identify them.
3. Small entity representatives should typically be involved in reviewing the draft compliance guide after the rule is promulgated so that we have the benefit of their comments and advice in preparing the final version of the guide.
 - a. With the exception stated below (b.), draft compliance guides should not be released to outside parties prior to the rule's promulgation.
 - b. In those unusual circumstances where the outline of the compliance guide is clear to the lead program at the pre-proposal stage, then they may seek review and feedback from small entity stakeholders at that stage.
 - c. You should share the draft compliance guide and solicit comment from small entity stakeholders after promulgation, but will need to balance such review with a commensurate concern for timely issuance of the guide.

D. When should I begin developing the guide and when will it need to be completed?

1. You should integrate development of the guide into the rulemaking process. Generally, begin work on your guide as soon as you have enough information to do so. This point will vary from rule to rule; sometimes it is clear even before the rule is proposed, and in other cases not enough is known until just prior to final promulgation. In either event, **you should not schedule additional time during the rulemaking process for development of the guide. The Agency will not ask for extension of any court deadlines in order to complete compliance guides.**

2. Keep in mind that the goal is to make the guide available after promulgation in sufficient time for it to be of practical help to small entities in evaluating and implementing their compliance options before the compliance deadline. You should make every effort to issue the guide within two months of the promulgation of the final rule.

E. What are the other timing considerations in developing and issuing the Guide?

1. The constraints on outside participation during the final rule phase in development of the Guide leave a relatively short time after promulgation to both take comment from small entity stakeholders and issue the final Guide. This makes advance planning and drafting essential.

Tip: Identify your small entity reviewers early in the process. You should consider using those small entity representatives who participated in the development of the proposed rule.

2. If the issuance of your guide may be delayed beyond a month or two, you should issue a Fact Sheet or other brief description of the rule as an interim measure.
3. If your rule has a distant compliance date (e.g., two years or more), you may want to re-issue the Guide closer to the compliance date.

F. What sorts of questions should I ask my small entity reviewers?

Some suggestions include:

- Is the format appropriate?
- Is the guide clear and easy to read and understand?
- Does the guide accurately describe the rule as published?
- Is the guide useful in planning for compliance?

G. How do I document development of the Guide?

1. If you are doing an Analytic Blueprint you should include plans for developing the guide, including a time line, and the resources needed. If there is no Blueprint, you should integrate it into your action or work plan.
2. When you submit your final rule to the Administrator for signature, you must also submit a schedule for development and completion of the compliance guide.
3. Include your distribution strategy for the guide in the Communications Plan. This is in

addition to your notification plan for the announcement of the rule.

4. Ultimately, the lead office will input information related to the development of the guide into OPPE's Regulatory Information System, which is currently under development. Lead offices may also develop internal methods for tracking the development of the guides.

H. What internal Agency concurrence do I need for the Guide and how do I get it?

You need concurrence from both OGC and OECA. Normally, you will ask members of your workgroup from these offices to assure that appropriate levels of management in their offices approve the draft. (OGC and OECA will determine the level of concurrence they need within their offices). If you don't have OGC and/or OECA members on your workgroup, contact your Steering Committee representative who will obtain/identify contacts for you.

I. When the Guide is in final form, who can help me with distribution?

1. In addition to internal office distribution mechanisms, you should provide Guides to the Office of the Small Business Ombudsman, the Office of Regional and State/Local Relations, the Office of Communications, Education and Public Affairs. These offices will distribute the Guide to their small entity contacts. (You should assure, to the extent it is feasible, that these offices do not have duplicate distribution lists.)
2. Distribution must be consistent with the recommendations of the Enhanced Public Access Task Force.
3. Other small business assistance providers include:
 - State Technical Assistance Programs for Pollution Prevention
 - State Small Business Assistance Programs
 - Small Business Development Centers
 - Manufacturing Extension Partnership Centers funded by NIST
 - Northeast Waste Management Officials Association
 - Illinois Hazardous Waste Research and Information Center
 - Waste Reduction Resource Center for the Southeast, and
 - the Small Business Administration, USDA and OSHA

J. How do we ensure that guides are kept up to date?

1. As a statutory matter, compliance guides may have evidentiary uses in litigation so it is important that guides be reviewed and revised as needed. It is the responsibility of the lead office to assure compliance guides are kept current. There is one case in which you must review an existing guide and several others when revisions may be desirable:

- a. Because we must generally review within ten years of promulgation any final rules for which we conducted regulatory flexibility analyses, the guide will be reviewed concurrently with the rule on or before the 10-year anniversary.
- b. Other circumstances which may occasion revisions include:
 - Changes in the rule which affect compliance
 - Comments from the public suggesting revisions, or from OECA based on their experience in enforcing the regulation. (See Appendix, Section C for instructions on soliciting customer feedback).
 - Litigation citing a guide as a reason to challenge the appropriateness of proposed penalties.
2. You should indicate in every guide that there may be subsequent revisions to the guide and include information about obtaining the revised guide. Place the most current guide in the appropriate docket, on a special section in EPA's internet page, or other electronic bulletin boards.

Note: OECA may, at a later date, develop sector-specific, multimedia guides which would integrate rule-specific guides. OECA will notify program offices if and when it undertakes this project and will coordinate development of such guides through the Agency's Regulatory Steering Committee.

II. TEMPLATE FOR COMPLIANCE GUIDES

An Agency workgroup has developed the following template to help you in structuring your compliance guide, and you should use it in accordance with the guidance given earlier in the chapter. While SBREFA does not mandate a particular format, we urge you to adopt it so that we may have general consistency across the Agency and to assure that significant compliance issues are adequately covered. If your rule does not, for some reason, lend itself to this template, you may use it as a checklist to ensure that all potentially relevant compliance issues are covered.

The template is organized as follows:

- Non-italicized text indicates sections which should normally be included in the compliance guide.
- We have also included standard language which you may choose to use if it is appropriate to your rule, and it is presented in *italics*. You should adapt this standard language to the specifics of your rule as necessary.
- Program offices have lead responsibility unless otherwise designated in **bold**.

Please make your best effort to write your guide in plain language using the guidance at <http://www.blm.gov/nhp/NPR/plaineng.html>.

[Insert standard publication header, including the date and appropriate publication number]

SMALL ENTITY COMPLIANCE GUIDE
[insert title of rule or program...]

I. INTRODUCTION

This document is published by the Environmental Protection Agency (EPA) as our official compliance guide for small entities, as required by the Small Business Regulatory Enforcement Fairness Act of 1996. Before you begin using the guide you should know that the information in this guide was compiled and published on [INSERT PUBLICATION DATE]. EPA is continually improving and upgrading its rules, policies, compliance programs, and outreach efforts. You can determine whether EPA has revised or supplemented the information in this guide by calling [INSERT HOTLINE NUMBER OR INTERNET ADDRESS].

A. Who Should Use this Guide?

1. To the extent possible, the guide should identify all the types/categories of small entities that will be subject to the rule's requirements. Bear in mind that other entities may be *indirectly* affected but may not be required to comply. This section needs to make this distinction clear to the reader.

Tip: Use the compliance table from the "Summary" section of your rule's preamble to convey this information. Be sure to modify it if necessary to target small entities.

2. In many cases, the guide will also be useful to larger entities subject to the rule. You may wish to point out any similarities or differences at this stage but you should not go into great detail on this subject.

B. What does the Guide Cover?

C. How do I use the Guide?

D. How do I Obtain a Complete Copy of the Rule?

List an 800 number, *Federal Register* citation or the Government Information Locator Service.

II. WHAT DOES THE REGULATION REQUIRE?

A. What environmental/human health issue(s) does this rule address and why it is important?

B. Summary of the New Regulation

1. Using plain English, summarize the rule in a narrative format. This should be a simplified adaptation of the issues you discussed in the rule's preamble.
2. Additionally, provide a visual description (e.g., chart or flowchart) of the rule's requirements as it applies to small entity operations or processes. "Operations" include traditional facility-based operations and non-traditional based operations such as farms, communities or schools.

C. Compliance Timetable

Identify in easy-to-read format (e.g., flowchart, time line, timetable) compliance dates for notifications and other requirements.

D. How Does this Regulation Relate to Other Federal, State, and Local Requirements?

1. Each Program should develop specific template language concerning program delegations and relationships to other requirements **generally**, or, where appropriate, referring back to general provisions applicable to all regulations in a subgroup to which the new regulation belongs (e.g., New Source Performance Standards under the Clean Air Act). Programs have the flexibility to expand this section as appropriate, to address this issue more **specifically**.
2. Meanwhile, here is suggested template language which may be appropriate in many cases:

This compliance guide explains your federal compliance obligations with respect to _____ rule. There may be other state or local requirements which apply to you which are different from, or more stringent than, the federal requirements. For example, some environmental statutes allow EPA to delegate environmental programs to a state. The state may then promulgate its own rules which may supersede the federal requirements. For more information on the rules that apply in your State, please contact [INSERT CONTACT POINT].

III. STEP-BY-STEP PROCEDURES FOR COMPLIANCE WITH THIS RULE

This is where you break down the rule into discrete subject areas using a step-by-step, question/answer approach. Questions in this section will depend on the particular rule. All the following questions are EXAMPLES of the types of questions that may be appropriate to include.

- A. How can I tell if I am subject to this rule?**
- B. What requirements am I subject to?**
- C. When do I need to comply ? (elaborate on flowchart, as appropriate)**
- D. What do I need to do to comply?**

Be sure to address such questions as:

- How does this rule affect my existing permit?
- How much will it cost to comply with this rule?

- E. What, when and how must I monitor or test?**
- F. What records do I need to keep and for how long?**

Include sample forms and calculations.

- G. What, when and to whom must I report?**

Include sample forms.

- H. How do I minimize harm if I think I am out of compliance? (Program lead/OECA support)**

- I. Where do I go for help?**

Give information on federal, State and local contacts, Agency hotlines, or State Small Business Assistance Program contacts.

- J. What is pollution prevention and how can it affect my operations? (OPPT lead)**

1. Discuss pollution prevention and its benefits, including how it may be used to help a facility/operation save money and/or possibly avoid regulation.
2. To the extent that there are other pollution prevention opportunities, including those

which may make good business sense or could exempt a small entity from certain requirements, the program, with support from OPPT, has the option to expand this section and include this information.

K. Are there opportunities for flexibility or waivers ?

If this is applicable in a given rule, these opportunities can be highlighted here. For example, there are circumstances in which the Safe Drinking Water Act allows temporary variances or exemptions from maximum contaminant levels.

IV. OPTIONAL QUESTIONS AND ANSWERS ABOUT FACILITY/OPERATIONS/PROCESSES

Here you want to anticipate questions of potential concern to the regulated community, including how the rule fits into the overall regulatory program. Questions will depend on the rule; the questions below are only EXAMPLES. [Tip: A self-audit checklist can be very helpful to small entities and may be used alone or in conjunction with a question and answer format.]

A. How do I conduct a self-audit of my facility/firm/operation to help me evaluate whether I am in compliance with this rule?

Provide Self-Audit Checklist (Program/OECA)

B. What are the implications of this rule for my existing permits?

Adapt this to your particular rule or program.

C. How Does this Rule Change How I Handle/ Store Wastes? (if guide were written for RCRA rule)

V. THE COMPLIANCE ASSURANCE PROCESS (OECA LEAD)

This section should describe in clear, non-threatening terms why compliance is important, the potential consequences of violating the law, and how the entity can work with us to identify and correct its compliance problems, often without the need for a formal enforcement action or penalty.

Draft this section to ensure that small entities understand:

- how EPA determines compliance
- what they must do if they discover a violation, and

- the available compliance assistance/enforcement options.

Include only information that is directly relevant to the rule. You may attach more detailed information, or information you feel may be helpful, in an Appendix.

A. How Is My Operation's Compliance With Environmental Requirements Determined?

Discuss compliance assistance, inspections, self-monitoring and the role of citizens.

B. If I Discover a Violation, How Can I Work With The Agency to Correct It?

Discuss compliance incentives policies: Small Communities Policy, Policy on Compliance Incentives for Small Businesses, Self-Disclosure Policy.

C. If the Agency Discovers a Violation, What Might Be Its Response?

To maximize compliance, EPA implements a balanced program of compliance assistance, compliance incentives, and traditional law enforcement. EPA knows that small businesses which must comply with complicated new statutes or rules often want to do the right thing, but may lack the requisite knowledge, resources, or skills. Compliance assistance information and technical advice helps small businesses to understand and meet their environmental obligations. Compliance incentives, such as our Small Business Policy, encourage persons to voluntarily discover, disclose, and correct violations before they're identified by the government. EPA's strong law enforcement program protects all of us by targeting persons who neither comply nor cooperate to address their problems.

EPA uses a variety of methods to determine whether businesses are complying, including inspecting facilities, reviewing records and reports, and responding to citizen complaints. If we learn a person is violating the law, EPA (or a State, if the program is delegated) may file an enforcement action seeking penalties of up to \$[INSERT STATUTORY MAXIMUM AMOUNT], per violation, per day. The proposed penalty in a given case will depend on many factors, including the number, length, and severity of the violations, the economic benefit obtained by the violator, and its ability to pay. EPA has policies in place to ensure penalties are calculated fairly. These policies are available to the public. In addition, any company charged with a violation has the right to contest EPA's allegations and proposed penalty before an impartial judge or jury.

In summary, EPA recognizes that we can achieve the greatest possible protection by encouraging small businesses to work with us to discover, disclose, and correct violations. That's why we've issued self-disclosure, small business, and small community policies to eliminate or reduce penalties for small and large entities

which cooperate with EPA to address compliance problems. In addition, we've established compliance assistance centers to serve over a million small businesses. For more information on these and other EPA programs for small businesses, please contact [INSERT POINT OF CONTACT].

D. What is the legal status of this guide?

A judge can look at a compliance guide in determining what penalty is appropriate and reasonable, although the content of the guide cannot otherwise be reviewed by the court.

In this Compliance Guide, we have tried to make clear what you must do to comply with the applicable law and regulation. This is the minimum required by SBREFA. You'll notice, however, that here and there we have also included suggestions for alternative approaches that may make compliance easier and possibly even reduce costs. We hope you find this presentation of regulatory requirements useful and the additional information helpful in reaching and maintaining compliance.

APPENDIX

A. Glossary of Environmental Terms

Define terms which are relevant to the rule but which may be too basic to be defined in the rule itself. For example, "permit," "pollution prevention," "process."

B. Where to Obtain More Information

This section gives supplemental information. Examples might include other existing quality compliance guidance, pollution prevention guidance, pollution prevention case studies, other media contacts, trade associations, or university assistance programs.

C. Questionnaire - How Useful Was This Guide?

Each guide should contain a brief questionnaire to solicit feedback from users as to the usefulness, readability, and improvements needed for the guide. Questionnaires will be returned to OPPE/RMD and then forwarded to the Agency contact. Please use the following page:

Date: _____

Title of Rule or Program: _____

Name of Commenter (optional): _____

Please take a moment to let us know if you found this guide useful by answering the following questions. Thank you, your feedback is important to us.

1. *I could easily understand what requirements I must meet.* _____
2. *The guide is written in understandable language.* _____
3. *The guide helped me understand the steps I must take to comply with the rule.* _____
4. *If you have suggestions to improve the guide, please indicate below:*

----- Please fold on dashed line, affix postage and return by mail. Thank-you. -----

Affix
Postage
Here

**U.S. EPA
Regulatory Management Division
Mail Code 2136
401 M St. SW
Washington, DC 20460**

Chapter 5

Congressional Review of Rules

Section	Subject	Page
I.	INTRODUCTION	1
II.	STATUTORY BACKGROUND	1
III.	AGENCY IMPLEMENTATION OF CONGRESSIONAL REVIEW PROVISIONS	7

I. INTRODUCTION

As discussed in previous chapters, SBREFA revamped various aspects of federal regulatory practice with respect to small entities. SBREFA also established a new mechanism for expedited congressional review of agency rules. This congressional review component of SBREFA is legally and conceptually distinct from SBREFA's small entity provisions. Congressional review applies to virtually any rule, whether or not the rule has any effect on small entities.

This chapter describes the congressional review provisions of SBREFA, the role of federal agencies in submitting rules for review, and the effect of congressional review and disapproval on rules. It also explains EPA's process for submitting Agency rules for review.

II. STATUTORY BACKGROUND

A. What is the purpose of congressional review?

In enacting subtitle E of SBREFA, Congress provided itself with an expedited means of reviewing and potentially disapproving final rules issued by federal agencies. Congress has always had authority to pass legislation rescinding an agency's rule. As long as the President does not veto such legislation, or Congress overrides any veto, the rule at issue is nullified. Before SBREFA, however, such legislation was subject to Congress' usual procedural rules, which ensure a careful -- but often lengthy -- review of legislative proposals. With SBREFA, a member of Congress can introduce a joint resolution to disapprove a particular rule within a specified period of time and have that joint resolution considered using expedited procedures. Moreover, for any rule meeting SBREFA's definition of "major rule", Congress has 60 days to act before the rule can take effect. SBREFA thus enables Congress to more effectively

oversee agency implementation of the laws Congress enacted.

B. What agency actions are subject to congressional review?

With several exceptions, all agency **final rules** are subject to congressional review. SBREFA defines “rule” by reference to section 551 of the Administrative Procedure Act (APA). Proposed rules are **not** subject to congressional review.

SBREFA exempts the following from the definition of rule:

- rules of particular applicability (i.e., rules applying to named entities);
- rules relating to agency management or personnel; and
- rules of agency organization, procedure or practice that do not substantially affect the rights or obligations of non-agency parties.

C. What is the agency’s role in congressional review?

Before a rule can take effect, the agency issuing the rule must submit to each House of Congress and to the Comptroller General of the United States a rule report containing:

- a copy of the rule;
- a concise general statement relating to the rule, including whether the rule is a “major rule;” and
- the proposed effective date of the rule.

At the same time, the agency must also submit to the Comptroller General and make available to each House of Congress:

- a complete copy of any cost-benefit analysis of the rule;
- the agency’s actions relevant to specified provisions the Regulatory Flexibility Act (RFA);
- the agency’s actions relevant to specified provisions of the Unfunded Mandates Reform Act (UMRA); and
- any other relevant information or requirements under any other Act and any relevant Executive Order.

D. What is a “major rule”?

A “major rule” is a rule that the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) finds has resulted in or is likely to result in:

- an annual effect on the economy of \$100 million or more;
- a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

E. How does SBREFA affect the effective date of rules?

1. In general

SBREFA generally provides that before a rule can take effect, a report containing a copy of the rule (described above) must be submitted to both Houses of Congress and the Comptroller General of the United States. Only the rule report must be submitted for the rule to take effect. While SBREFA requires that any cost-benefit analysis and information about agency compliance with the RFA, UMRA, etc., be submitted at the same time as the report, it does not make the rule’s effective date contingent on submission of this additional information.

Once the rule report has been submitted to Congress and the Comptroller General, a rule that is **not major** under SBREFA may take effect as it otherwise would under applicable law. A rule that is **major** under SBREFA may take effect **no earlier than 60 days** after the agency submits the rule report for congressional review or the rule is published in the Federal Register, whichever is later.¹⁸

If a joint resolution of disapproval is enacted with respect to either a non-major or major

¹⁸ If Congress passes a joint resolution disapproving a major rule within the 60-day period following the rule’s submittal or publication, **and** the President vetoes the joint resolution, the rule’s effective date is delayed somewhat longer to provide Congress with an opportunity to override the President’s veto without the rule taking effect in the interim. The delay is extended until either House of Congress votes and fails to override the veto or 30 session days have passed without either House taking action on the veto, whichever is earlier. If Congress fails to act within 30 session days, the rule may take effect as it otherwise would, although Congress may still override the veto. Congress may also pass a joint resolution of disapproval after the 60-day period following the rule’s submittal or publication, but passage of a resolution after the 60-day period does not extend the delay of the rule’s effective date. The rule may take effect after the 60-day period as it otherwise would.

rule, the rule cannot take effect or, if the rule has taken effect, it cannot continue in effect and is deemed to have never taken effect.

2. Exceptions

SBREFA provides several exceptions to its delay of the effective date of rules subject to congressional review. Two of the exceptions are potentially applicable to EPA rules. First, a **non-major or major rule** may take effect as it otherwise would when the issuing agency for good cause finds that notice-and-comment rulemaking procedures for that rule are “impracticable, unnecessary, or contrary to the public interest.”¹⁹ The agency must incorporate the finding and an explanation of the finding in the rule’s issuance.

Second, a **major rule** may take effect before it otherwise would under SBREFA where the President makes a determination by Executive Order that the rule should take effect because such rule is

- necessary because of an imminent threat to health or safety or other emergency;
- necessary for the enforcement of criminal laws;
- necessary for national security; or
- issued pursuant to any statute implementing an international trade agreement.

The President must submit written notice of the determination to Congress.

A rule qualifying for either of these exemptions may thus take effect prior to being submitted to Congress (and in the case of major rules, prior to the expiration of the 60-day period that would otherwise apply). However, **rules qualifying for either exemption must still be submitted for congressional review.**

It should also be noted that these exemptions provide relief only from SBREFA’s delay of the effective date of rules. They do not and cannot “resuscitate” a rule that has been nullified by an enacted joint resolution of disapproval. For example, a major rule exempted from SBREFA’s 60-day delay provision by an Executive Order may nonetheless be nullified by a joint resolution of disapproval that Congress enacts either with the President’s consent or over his veto.

F. **What is the effect of congressional disapproval?**

¹⁹This is the same finding an agency makes to exempt a rule from APA notice-and-comment requirements that would otherwise apply. This is **not** the same finding an agency makes to exempt a rule subject to the APA from the general APA requirement that a final rule be published not less than 30 days before its effective date.

1. On the rule

As indicated above, enactment of a joint resolution of disapproval nullifies the rule. Enactment requires passage by both Houses of Congress and presentment to the President; if the President vetoes the resolution, Congress must override the veto by two-thirds vote of each House. If a resolution is enacted **before** the rule has taken effect, the rule cannot take effect. If a resolution is enacted **after** the rule has taken effect, the rule cannot continue in effect and is treated as though it had never taken effect.

2. On statutory or court-ordered deadlines

SBREFA provides that "any deadline for, relating to, or involving" a disapproved rule is extended "until the date [one] year after the enactment of the joint resolution" disapproving the rule. In the case of a final rule subject to a statutory or court-ordered deadline, disapproval of the rule thus extends the deadline for one year.

3. On the agency's authority to issue a replacement rule

SBREFA expressly provides that an agency may not reissue a disapproved rule in "substantially the same form," unless specifically authorized to do so by a law enacted after the date of the joint resolution disapproving the original rule.

G. How does Congress review rules under SBREFA?

This portion of the outline covers SBREFA provisions that govern Congress and the Comptroller General, not agencies. Knowledge of these provisions may nevertheless provide useful perspective for developing rules.

1. Distribution to congressional committees

Upon receiving a rule report, each House of Congress is directed to provide a copy of the report to the congressional committees with jurisdiction to report a bill to amend the law under which the rule was issued.

2. Reports on major rules

For any major rule, the Comptroller General, who heads the General Accounting Office (GAO), must provide a report on the rule to the relevant committees of Congress within 15 days of the rule's publication in the Federal Register or its receipt by Congress, whichever is later. The GAO report is to include an assessment of the agency's compliance with the procedural steps required by the RFA, UMRA and other relevant statutes and executive orders, including SBREFA, the Paperwork Reduction Act and E.O. 12866. The agency issuing the major rule is directed to cooperate with the GAO by providing information relevant to preparation of the GAO report.

3. Limited window for introduction of joint resolution of disapproval

To take advantage of SBREFA's expedited procedures for review of agency rules, a member of Congress must introduce a joint resolution of disapproval within a specified time period. Generally, this period is 60 days (not counting those days either House of Congress is adjourned for more than 3 days) beginning on the date Congress receives the report containing a copy of the rule. However, if the rule is submitted to Congress within 60 session days (in the Senate) or 60 legislative days (in the House) before Congress adjourns a session, members of Congress have until the 15th session day (in the Senate) and the 15th legislative day (in the House) of the next session of Congress to introduce a joint resolution.

4. Form of joint resolutions of disapproval

For SBREFA purposes, a joint resolution of disapproval is defined as a resolution that states after the resolving clause, "That Congress disapproves the rule submitted by the _____ relating to _____, and such rule shall have no force or effect" (the blank spaces being appropriately filled in). A joint resolution of disapproval may thus only nullify a rule in full. It may not be used to rescind part of a rule or add to or revise provisions of the rule.

5. Congressional consideration of joint resolutions

When a joint resolution of disapproval is introduced in the Senate, specified procedures for considering the resolution apply in the Senate for 60 session days after Congress' receipt of the agency's rule report or publication of the rule in the Federal Register, whichever is later. In the case of a rule submitted within 60 session days of Congress adjourning for a session, the Senate's expedited procedures apply until the expiration of the 60th session day following the 15th session day of the next session of Congress. Once the time period for the Senate's expedited procedures expires, any joint resolution may be considered using the Senate's normal procedures.

SBREFA is silent with respect to what procedures apply in the House of Representatives when a joint resolution of disapproval is introduced by a member of that House. However, SBREFA does specify the procedures that apply when one House receives a joint resolution passed by the other House before it has passed its own. In that instance, the receiving House is **not** to refer the joint resolution passed by the other House to a committee. The receiving House is to apply its own procedures to consideration of the joint resolution and take any vote on the other House's resolution. SBREFA sets no deadline for Congressional action on a resolution once introduced.

III. AGENCY IMPLEMENTATION OF CONGRESSIONAL REVIEW PROVISIONS

A. What agency actions are covered?

1. Generally applicable rules

With a few exceptions noted below, any generally applicable rule must be submitted to Congress and the Comptroller General. A generally applicable rule is a rule that a) applies to entities that meet specified criteria (as opposed to entities individually named by the rule), and b) is binding on those entities subject to it (i.e., would be the basis for an enforcement action). If a rule applies to entities identified by criteria and is legally binding on those entities, it must be submitted to Congress for review. For example, a rule that names and imposes a requirement on only Acme Manufacturing need not be submitted because it is a "rule of particular applicability" and thus not generally applicable. On the other hand, a rule that imposes a requirement on all manufacturers of a specified type or size would have to be submitted.

Whether an Agency action is a rule or an informal adjudication is not always clear. Some routine actions are in fact informal adjudications, so this issue should be considered in determining whether an action is subject to congressional review.

Rules that pertain only to internal Agency management and personnel issues are not subject to review and should not be submitted. Rules that address Agency organization, practice or procedure are subject to review only if they substantially affect the rights or obligations of non-agency parties.

2. Technical correction rules

There is no exemption from the submission requirement for "technical correction" rules. A technical correction rule corrects minor errors of a clerical or technical nature (e.g., a typographical error) in an existing rule. It is worth noting, however, that these rules are typically eligible for the APA "good cause" exemption from notice-and-comment rulemaking requirements. Because they are minor in nature, it is generally unnecessary to provide prior public notice and comment on them. The rules are thus also eligible for the "good cause" exception from the effective date delay provisions of SBREFA, since the finding required under SBREFA is the same as that required under the APA. However, to qualify for both exceptions, the preamble of the rule must include the "good cause" finding explaining why prior public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest.²⁰

For technical correction rules, the following language should be included in the preamble

²⁰As noted elsewhere, the "good cause" finding necessary to exempt a rule from SBREFA's delay of effective dates is **not** the same "good cause" finding necessary to exempt a rule from the APA's 30-day delay of effective dates. Thus, for a technical correction rule that is subject to the APA and that the Agency wants to make effective earlier than 30 days after publication, the Agency must make two "good cause" findings in the preamble of the rule -- one explaining why prior notice and comment are impracticable, unnecessary or contrary to the public interest, and the other explaining why the rule should take effect earlier than 30 days after publication.

of the rule to address the reporting requirements of SBREFA. This language is **in addition to** the findings discussed above and the language specified in the last section of this chapter.

Under Executive Order 12866, this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose annual costs of \$100 million or more, will not significantly or uniquely affect small governments, and is not a significant federal intergovernmental mandate. The Agency thus has no obligations under sections 202, 203, 204 and 205 of the Unfunded Mandates Reform Act. Moreover, since this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to sections 603 or 604 of the Regulatory Flexibility Act.

3. Direct final rules and withdrawals thereof

Direct final rules should be submitted for congressional review since they become final unless the Agency withdraws them. Withdrawals of direct final rules need not be submitted, since withdrawals are not rules.

B. How should the effective date of a rule be determined in light of SBREFA?

As explained above, SBREFA generally provides that before a rule subject to congressional review can take effect, it must be submitted to Congress and the Comptroller General. A major rule generally cannot take effect earlier than 60 days after it is submitted to Congress or published in the Federal Register, whichever is later. Moreover, SBREFA's effective date provisions override inconsistent provisions in laws that predate SBREFA. For example, even if a preexisting statute would allow a rule meeting SBREFA's major rule definition to take effect upon promulgation, under SBREFA the rule may **not** take effect earlier than 60 days following the later of its submittal to Congress or its publication in the Federal Register, unless one of the exceptions from SBREFA's effective date provisions apply. Accordingly, SBREFA must be considered in determining the effective date of any rule subject to congressional review.

EPA has instituted a process by which any rule subject to congressional review under SBREFA is submitted to the Hill at the same time it is submitted to the Federal Register for publication. This process ensures that rules are always submitted to Congress by the time they are published in the Federal Register. Thus, EPA may accurately determine a rule's effective date under SBREFA (barring enactment of a joint resolution disapproving the rule) and include that information in the Federal Register notice of the rule.

By virtue of EPA's submission process, a rule that is **not major** under SBREFA may

take effect as early as the date it is published in the Federal Register consistent with SBREFA.²¹ A non-major rule may take effect as early as the date it is promulgated,²² even **before** it is published or submitted to Congress, if the Agency invokes the “good cause” exception from SBREFA’s effective date provisions. As described above, to invoke that exception, the Agency must publish along with the rule a finding that prior public notice and comment procedures for the rule are unnecessary, impracticable or contrary to the public interest. It should be noted that even where public notice and comment were provided for a rule, it may be possible to make a finding that providing public notice and comment was unnecessary, depending on the particular circumstances of the rule.

Again by virtue of EPA’s submission process, a rule that is **major** under SBREFA may take effect as early as 60 calendar days after the rule is published in the Federal Register consistent with SBREFA. A major rule may take effect as early as the date it is published or promulgated if the Agency invokes one of two exceptions from SBREFA’s effective date provisions. The first exception is the same as that described above in the context of non-major rules -- where the agency finds, and explains in the rule’s preamble, that providing prior public notice and comment on the rule is unnecessary, impracticable or contrary to the public interest. The second exception is for major rules for which the President makes a determination by Executive Order that the rule should take effect earlier than it otherwise could under SBREFA.

C. What materials must be submitted beside the rule itself?

As described above, SBREFA requires that a report containing a copy of the rule and other specified information be submitted for congressional review before the rule can take effect. It also requires that additional information pertaining to the rule be submitted to the Comptroller General and made available to Congress at the same time the rule is submitted.

The Regulatory Management Division (RMD) of OPPE has developed a form (attached) that covers all of the information that needs to be submitted with the rule. Once the form is filled out and a copy of the rule and any other specified documents are attached, the rule is ready for submission to the Hill.

D. What are the procedures for submitting the rule to the Hill?

As noted above, the Agency’s practice is to submit any rule subject to congressional review to Congress and the Comptroller General at the same time it submits the rule to the Federal Register for publication. Accordingly, a rule subject to congressional review must be ready for submission by the time it is sent to the Federal Register. To make sure this occurs, the

²¹Whether the rule may take effect upon promulgation or publication consistent with the statute authorizing the rule or the APA is a separate issue.

²²Promulgation occurs when a rule is signed by the Administrator or other authorized Agency official and broadly disseminated to the public.

program office developing the rule must submit to RMD along with the Federal Register package for the rule: 1) the congressional submission form filled out for the rule, and 2) a copy of all of the documents that the form indicates must be submitted along with the Federal Register package. Where the documents are incorporated into the Federal Register package itself, they need not be supplied separately. However, where the Federal Register package only summarizes the relevant documents, a copy of the documents themselves should be provided.

RMD submits the required rule report and any accompanying information to both Houses of Congress and the Comptroller General. All congressional submissions under SBREFA should thus be routed through RMD. When RMD delivers the report and information to the appropriate Hill offices, it obtains a receipt for the submission and keeps a record of the date of receipt for purposes of establishing when the rule was submitted.

E. What should be included in the rule's preamble with regard to congressional review?

For any rule subject to congressional review, the preamble for the final rule should contain the following statement (which requires tailoring in one respect as indicated):

Submission to Congress and the Comptroller General

Under 5 U.S.C. §801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in today's Federal Register. This rule is [OR is not] a "major rule" as defined by 5 U.S.C. §804(2).

THIS PAGE INTENTIONALLY BLANK -- RESERVED FOR ATTACHMENT

Chapter 6:

[Ed. Note: Guidance Forthcoming for Informal Small Entity Guidance (SBREFA §213)]

TITLE II--SMALL BUSINESS REGULATORY FAIRNESS

SEC. 201. SHORT TITLE.

This title may be cited as the "Small Business Regulatory Enforcement Fairness Act of 1996".

*

*

*

SEC. 213. INFORMAL SMALL ENTITY GUIDANCE.

(a) General.--Whenever appropriate in the interest of administering statutes and regulations within the jurisdiction of an agency which regulates small entities, it shall be the practice of the agency to answer inquiries by small entities concerning information on, and advice about, compliance with such statutes and regulations, interpreting and applying the law to specific sets of facts supplied by the small entity. In any civil or administrative action against a small entity, guidance given by an agency applying the law to facts provided by the small entity may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages sought against such small entity.

(b) Program.--Each agency regulating the activities of small entities shall establish a program for responding to such inquiries no later than 1 year after enactment of this section, utilizing existing functions and personnel of the agency to the extent practicable.

(c) Reporting.--Each agency regulating the activities of small business shall report to the Committee on Small Business and Committee on Governmental Affairs of the Senate and the Committee on Small Business and Committee on the Judiciary of the House of Representatives no later than 2 years after the date of the enactment of this section on the scope of the agency's program, the number of small entities using the program, and the achievements of the program to assist small entity compliance with agency regulations.

Chapter 7:

[Ed. Note: Guidance Forthcoming for Periodic Review of Rules (RFA §610)]

REGULATORY FLEXIBILITY ACT

*
*
*

SEC. 610. PERIODIC REVIEW OF RULES.

(a) Within one hundred and eighty days after the effective date of this chapter, each agency shall publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities. Such plan may be amended by the agency at any time by publishing the revision in the Federal Register. The purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities. The plan shall provide for the review of all such agency rules existing on the effective date of this chapter within ten years of that date and for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule. If the head of the agency determines that completion of the review of existing rules is not feasible by the established date, he shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years.

(b) In reviewing rules to minimize any significant economic impact of the rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the agency shall consider the following factors--\

- (1) the continued need for the rule;
- (2) the nature of complaints or comments received concerning the rule from the public;
- (3) the complexity of the rule;
- (4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and
- (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

(c) Each year, each agency shall publish in the Federal Register a list of the rules which have a significant economic impact of a substantial number of small entities, which are to be reviewed pursuant to this section during the succeeding twelve months. The list shall include a brief description of each rule and the need for and legal basis of such rule and shall invite public comment upon the rule.